App. No. 10/665,873
Filed: September 18, 2003
Inventor: MINSHULL, et. al.
Docket No. USAV2001/0079 US NP

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATI
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT

(51) International Patent Classification 6 : A61M 15/00 | A2

(11) International Publication Number: WO 97/30743

(43) International Publication Date: 28 August 1997 (28.08.97)

(21) International Application Number: PCT/US97/01562

(22) International Filing Date: 13 February 1997 (13.02.97)

(30) Priority Data:
08/604,549 21 February 1996 (21.02.96) US

(71) Applicant: SCHERING CORPORATION [US/US]; 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 (US).

(72) Inventors: AMBROSIO, Thomas, J.; 31 Eastern States Parkway, Sommerville, NJ 08876 (US). BENSON, Warren, A., Jr.; 980 280th Street, Woodville, WI 54028 (US). DAO, Kim, C.; 25 Fern Terrace, Wayne, NJ 07470 (US). KENYON, David, J.; 4 Log Road, Morristown, NJ 07960 (US). KREISEDER, Walter, J.; 21650 Sylvander, Barrington, IL 60010 (US). SCHONEBAUM, Theodore, J.; 3003 Wilson Street, Lot 76, Monomonie, WI 54751 (US). VOGEL, Allen, J.; 5729 Butler Lane, Long Grove, IL 60047 (US). WALKER, Louis, B.; 809 24th Street, Menomonie, WI 54751 (US). YANG, Tsong-Toh; 9 Old Farm Road, Warren, NJ 07059 (US).

(74) Agents: FRANKS, Robert, A. et al.; Schering-Plough Corporation, Patent Dept. K-6-1 1990, 2000 Galloping Hill Road, Kenilworth, NJ 07033-0530 (US).

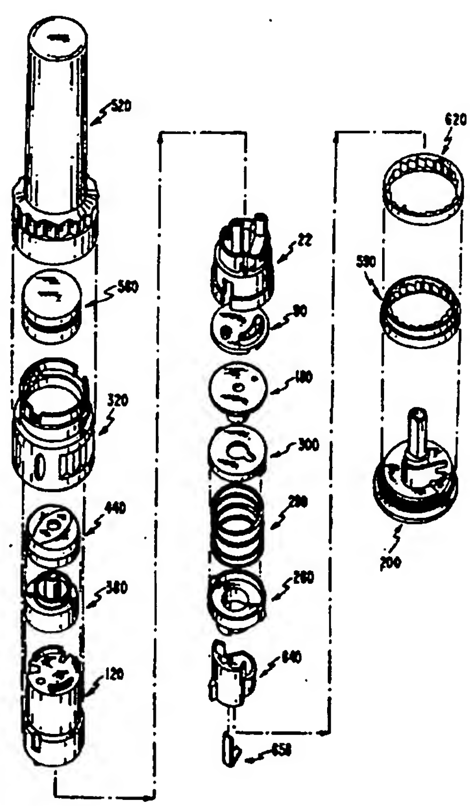
(81) Designated States: AL, AM, AU, AZ, BA, BB, BG, BR, BY, CA, CN, CZ, EE, GE, HU, IL, IS, JP, KG, KR, KZ, LC, LK, LR, LT, LV, MD, MG, MK, MN, MX, NO, NZ, PL, RO, RU, SG, SI, SK, TJ, TM, TR, TT, UA, UZ, VN, YU, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: POWDERED MEDICATION INHALER

(57) Abstract

A powder dispenser includes a reservoir body including a supply of powder and an inhalation conduit; a driving body for rotating the reservoir body and including upper recesses and two spring fingers in lower driving recesses thereof; a rotatable metering plate for carrying a metered amount of powder from the supply to theinhalation conduit, and having an underside with ribs; a gas permeable retainer welded to the ribs; a spring biasing the metering plate toward the reservoir body; a nozzle having spiked ribs welded in the upper recesses of the driving body and including a chimney with vertical flutes; an adapter non-rotatably mounted with respect to the metering plate and including two locking recesses for receiving the spring fingers for locking engagement and two helical cam tracks with a square cross section; a closure cap covering the driving body and including priming ribs biasing the spring fingers out of the locking recesses and engaging with the locking recesses to rotate the driving body, and two cams riding within the cam tracks; a base non-rotatably connected with the metering plate; and a counter rotatably mounted on the base and including rotatable counter rings providing a visual count of the number of doses of powder to be dispensed, and a pawl assembly engaging with gear teeth of the counter rings for rotating the same, the pawl assembly including an outer wall, a pawl and a pawl spring integrally molded as a single piece.



POWDERED MEDICATION INHALER

INTRODUCTION TO THE INVENTION

The present invention relates generally to powder dispenser assemblies and, more particularly, is directed to a powder dispenser assembly used for inhalation of a metered dose of a powdered medicament.

When delivering medicaments, that is, pharmacologically active compounds, in solid form to the respiratory tract and to the lungs, careful attention to the accuracy of the dosage, which can be smaller than 0.1 milligram, must be made. This is because such medicaments are often quite potent, and the administration of excessive amounts thereof could be harmful to the patient. Further, if the dosage that is delivered is too small, it will not serve its purpose.

It is also necessary that the particles leaving the dispenser assembly be substantially within a particular size range, since particles of the medicament which are too large may not enter a desired lower portion of the respiratory tract, such as the bronchial tree or lungs, but instead will be deposited in the mouth or pharynx and thence enter the digestive tract. As an example, preferred particles usually are considered as having a diameter less than about 10 micrometers.

Various devices have been used in order to dispense a metered dose of powdered medicament,

fraction from the powder dispenser of the aforementioned international application for a formulation of mometasone/lactose agglomerates having a component weight ratio of 1:5.8 provides only about 10% of total particles having diameters less than about 6.8 micrometers. It has been determined that one of the likely reasons for this is the swirl nozzle design which does not sufficiently break up the hard agglomerates.

Another potential problem with such design is that the screw threads on the cap and adapter provide a condition in which the cap may be prematurely pulled off due to the tolerances of the screw threads. As a result, the dispenser may not be turned a full 180°, as required. Thus, the proper dosage may not be provided, and the counter mechanism may not be activated. Further, by prematurely pulling the cap off, it may not be possible to easily reapply the cap to the dispenser to close the same.

Also, positioning of the cap for the rotating operation may not always result in accurate alignment.

Another possible problem is that of securing the powder retainer to the metering dose plate. If a hot melt adhesive is used, the adhesive may leak into the mesh, so that quality and consistency is not obtained. Further, by heating the same, there may be a distortion in the flatness and/or damage to the mesh.

A yet further potential problem is that the pawl used in the counter mechanism of the primary embodiment thereof requires an additional metal spring to be inserted therein. This increases the number of parts, makes assembly more difficult, provides a pawl assembly that is not totally moldable and does not always provide a totally reliable counter mechanism. Although a totally molded spring and pawl assembly is disclosed in a later embodiment thereof, such totally molded spring and pawl assembly is more difficult to mold and

substantially continuously changing the direction of flow of the powder in the second direction in the cavity; and a chimney extending from the top wall in surrounding relation to the opening for changing the direction of flow of the powder from the second direction of the cavity substantially back to the first direction, the chimney extending along an axial direction thereof and including an inner tubular wall surface having irregularities extending in the axial direction.

Preferably, the irregularities are formed by a plurality of flutes on the inner tubular wall surface, and the flutes are formed by a plurality of first concave wall sections extending in the axial direction and having an arc of a first radius in a direction transverse to the axial direction, and a plurality of second wall sections extending in the axial direction and interconnecting the first concave wall sections, the second wall sections being of a concave configuration having an arc of a second radius in a direction transverse to the axial direction, the second radius being greater than the first radius.

The top wall has a circular shape and the opening is centrally located in the top wall, and the swirl wall includes a curved wall extending from the opening to the skirt, the curved wall extending in a substantially spiral manner and being connected with the top wall.

In accordance with another aspect of the present invention, a powder dispenser includes a powder housing for holding a supply of powdered material to be dispensed, the powder housing including an inhalation conduit extending therethrough in a first direction, in displaced relation to the supply of powdered material, the powder housing including a reservoir body including the supply of powdered material and the inhalation conduit, and a driving body secured to the reservoir

includes an adapter non-rotatably mounted with respect to the metering plate, the adapter including at least one locking recess for receiving the at least one spring finger therein to prevent rotation of the powder housing relative to the adapter and the metering plate; and a closure cap for covering the powder housing and for priming the powder dispenser for use, the closure cap including priming ribs for rotating the powder housing such that the inhalation conduit is in communication with the metered dose hole when the closure cap is removed from covering relation of the powder housing and for rotating the powder housing such that the inhalation conduit is out of communication with the metered dose hole when the closure cap is secured in covering relation to the powder housing, the priming ribs biasing the at least one spring finger out of the at least one locking recess of the adapter to enable rotation of the powder housing relative to the metering plate and for engaging with the at least one driving recess to rotate the powder housing relative to the metering plate.

Specifically, the driving body includes two diametrically opposite spring fingers, the adapter includes two diametrically opposite locking recesses and the cap includes at least two diametrically opposite priming ribs.

Each priming rib includes an upper ramp portion and a lower ramp portion which meet at an intermediate projecting portion and reduce in thickness as they move away from the projecting portion, such that the upper ramp portion initially biases the at least one spring finger out of the at least one locking recess during removal of the closure cap from the covering relation and the lower ramp portion initially biases the at least one spring finger out of the at least one locking recess during securement of the closure cap to the covering relation.

screen, a porous material mesh and a perforated plate element, and is ultrasonically welded to the ribs.

Preferably, the ribs are formed in a plurality of spaced apart, concentric circles, and each rib has a substantially triangular cross-sectional configuration.

In accordance with a still further aspect of the present invention, a method of forming a modified metering plate and gas permeable retainer thereon, includes the steps of positioning the gas permeable retainer at a predetermined position in a first mold half used for injection molding the metering plate; positioning a second mold half adjacent the first mold half to form a molding chamber therebetween used for injection molding the metering plate, the second mold half having a through opening therein in alignment with the retainer at the predetermined position in the first mold half; inserting a core pin through the through opening in the second mold half into engagement with the retainer to hold the retainer in position against the first mold half and to form a metered dose hole in the molded metering plate; and injecting plastic material into the molding chamber through at least one injection port to form the metering plate with the metered dose hole and with the retainer being secured to an underside of the metering plate in covering relation to the metered dose hole.

In such case, the molded metering plate has a shallow recess formed at the underside thereof in surrounding relation to the metered dose hole, and the powder retainer has dimensions greater than the metered dose hole to completely cover the metered dose hole and less than the shallow recess so as to be secured to the metering plate in the shallow recess.

In accordance with a yet further aspect of the present invention, in addition to the aforementioned powder dispenser including the powder housing having the reservoir body and the driving body, the metering

counting indicia of the intermittent counter ring through the display, the pawl assembly including an outer wall having an outer surface and an inner surface, a pawl, integrally molded as a single piece with the outer surface of the outer wall, for engagement within the gear teeth of one of the continuous counter ring and the intermittent counter ring, and a pawl spring, integrally molded as a single piece with the inner surface of the outer wall, for biasing the pawl into engagement with the gear teeth of the continuous counter ring and the intermittent counter ring, the pawl spring extending along a generally radial direction.

In one embodiment, the pawl spring has a generally L-shaped configuration. In another embodiment, the pawl spring has a generally linear configuration and extends at an angle from the inner surface of the outer wall. In either case, the pawl spring has one end integrally molded with an upper portion of the inner surface of the outer wall.

The above and other features of the invention will become readily apparent from the following detailed description thereof which is to be read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a metered powder dose dispenser according to the present invention;

Fig. 2 is a perspective view of the metered powder dose dispenser of Fig. 1, with the closure cap removed;

Fig. 3 is an exploded perspective view of the metered powder dose dispenser of Fig. 1;

Fig. 4 is a longitudinal cross-sectional view of the metered powder dose dispenser of Fig. 1;

Fig. 22 is a top plan view of the metering dose plate of the metered powder dose dispenser of Fig. 1;

Fig. 22A is a cross-sectional view of the metering dose plate of Fig. 22, taken along line 22A-22A thereof;

Fig. 22B is a cross-sectional view of the metering dose plate of Fig. 22, taken along line 22B-22B thereof, along with the mold for forming the same in dashed lines;

Fig. 22C is an enlarged cross-sectional view of a portion of the metering dose plate of Fig. 22B;

Fig. 23 is a bottom plan view of the metering dose plate of Fig. 22;

Fig. 24A is a top plan view of a modified metering dose plate;

Fig. 24B is a bottom plan view of the metering dose plate of Fig. 24A;

Fig. 24C is a cross-sectional view of the metering dose plate of Fig. 24A, taken along line 24C-24C thereof;

Fig. 24D is a cross-sectional view of the metering dose plate of Fig. 24B, taken along line 24D-24D thereof;

Fig. 24E is an enlarged cross-sectional view of a portion of the metering dose plate of Fig. 22D;

Fig. 24F is an enlarged cross-sectional view of a portion of the metering dose plate of Fig. 22E;

Fig. 25 is a top plan view of the base of the metered powder dose dispenser of Fig. 1;

Fig. 26 is a bottom plan view of the base of Fig. 25;

Fig. 27 is a front elevational view of the base of Fig. 25;

Fig. 28 is a side elevational view of the base of Fig. 25;

Fig. 29 is a cross-sectional view of the base of Fig. 25, taken along line 29-29 thereof;

Fig. 45 is an enlarged cross-sectional view of a portion of the adapter of Fig. 41, showing the window thereof;

Fig. 46 is a top plan view of the swirl nozzle of the metered powder dose dispenser of Fig. 1;

Fig. 47 is a bottom plan view of the swirl nozzle of Fig. 46;

Fig. 48 is a side elevational view of the swirl nozzle of Fig. 46;

Fig. 49 is a cross-sectional view of the swirl nozzle of Fig. 47, taken along line 49-49 thereof;

Fig. 50A is an enlarged bottom plan view of the center of swirl nozzle of Fig. 46;

Fig. 50B is a cross-sectional view showing securement of the swirl nozzle to the driving body;

Fig. 51 is a top plan view of the mouthpiece of the metered powder dose dispenser of Fig. 1;

Fig. 52 is a cross-sectional view of the mouthpiece of Fig. 51, taken along line 52-52 thereof;

Fig. 53 is a cross-sectional view of the mouthpiece of Fig. 51, taken along line 53-53 thereof;

Fig. 54 is a bottom plan view of the mouthpiece of Fig. 51;

Fig. 55 is a side elevational view of the mouthpiece of Fig. 51;

Fig. 56 is a side elevational view of the closure cap of the metered powder dose dispenser of Fig. 1;

Fig. 57 is a bottom plan view of the closure cap of Fig. 56;

Fig. 58 is a top plan view of the closure cap of Fig. 56;

Fig. 59 is a cross-sectional view of the closure cap of Fig. 57, taken along line 59-59 thereof;

Fig. 60 is a cross-sectional view of the closure cap of Fig. 58, taken along line 58-58 thereof;

Fig. 75 is a top plan view of the pawl assembly of the metered powder dose dispenser of Fig. 1;

Fig. 76 is a bottom plan view of the pawl assembly of Fig. 75;

Fig. 77 is a side elevational view of the pawl assembly of Fig. 75;

Fig. 78 is a rear elevational view of the pawl assembly of Fig. 75;

Fig. 79 is a cross-sectional view of the pawl assembly of Fig. 75, taken along line 79-79 thereof;

Fig. 80 is a top plan view of a pawl assembly according to another embodiment of the present invention;

Fig. 81 is a bottom plan view of the pawl assembly of Fig. 80;

Fig. 82 is a side elevational view of the pawl assembly of Fig. 80;

Fig. 83 is a cross-sectional view of the pawl assembly of Fig. 80, taken along line 83-83 thereof;

Fig. 84 is a top plan view of the pawl assembly according to another embodiment of the present invention;

Fig. 85 is a bottom plan view of the pawl assembly of Fig. 84;

Fig. 86 is a side elevational view of the pawl assembly of Fig. 84;

Fig. 87 is a cross-sectional view of the pawl assembly of Fig. 84, taken along line 87-87 thereof;

Fig. 88 is a cross-sectional view of the pawl assembly of Fig. 84, taken along line 88-88 thereof;

Figs. 89A-89E are longitudinal cross-sectional drawings of a portion of the metered powder dose dispenser, showing closing of the cap during sequential times; and

Figs. 90A and 90B are enlarged cross-sectional drawings of a portion of the metered powder dose

limited to these particular angles. Drive slots 34 and 36 are open at their lower ends 38 and 40, respectively, and extend upwardly entirely through lower annular skirt portion 30 and partially through upper annular skirt portion 28. Thus, drive slots 34 and 36 have closed upper ends which define seating edges 42 and 44.

Powder housing 20 includes an arcuate manifold 46 formed on the upper surface of circular top wall 24, at a peripheral position offset from the center thereof. Manifold 46 includes an arcuate chamber 47 extending circumferentially for an arcuate length of approximately 140° about a peripheral portion of circular top wall 24 and which is defined by a surrounding chamber wall 48. Specifically, chamber wall 48 is formed by a lower chamber wall portion 50 extending upwardly from circular top wall 24 and an upper chamber wall portion 52 extending upwardly from the upper end of lower chamber wall portion 50. The shapes of wall portions 50 and 52 are substantially identical, but with the inner dimensions of upper wall portion 52 being less than the inner dimensions of lower wall portion 50. As a result, a shoulder 54 is formed at the lower end of upper chamber wall portion 52.

Circular top wall 24 includes an opening 55 of the same shape and dimensions as lower chamber wall portion 50 of manifold 46 and in alignment with the lower end of lower chamber wall portion 50. The upper end of manifold 46, and particularly upper chamber wall portion 52, is closed by a manifold top wall 56 which is angled downwardly from the center thereof and which has an opening 58 at the center thereof.

A powder supply conduit 60 is formed on manifold top wall 52 at the center thereof in alignment with opening 58. The upper end of powder supply conduit 60 is open. Powder supply conduit 60 is normally filled

extend inwardly from opposite ends of securing wall 74 at gap 76. Further, a radially extending annular lip 80 extends outwardly from the upper end of securing wall 74.

As will be understood from the description hereinafter, it is necessary that the lower surface of circular top wall 24 be as smooth as possible, that is, with very few undulations therein. However, this is difficult to achieve when molding reservoir body 22 as a single piece. Therefore, to overcome this problem, a reservoir plug 90 is provided, as shown in Figs. 3 and 9-13.

Specifically, reservoir plug 90 includes a thin circular plate 92 which can be molded, because of the thinness of plate 92, to have a very smooth lower surface with no undulations. The outer diameter of circular plate 92 is substantially equal to the inner diameter of upper annular skirt portion 28 so that reservoir plug 90 can be fit therein, as shown in Fig. 4. In such condition, the lower surface of circular plate 92 effectively is flush with seating edges 42 and 44 of drive slots 34 and 36.

Circular plate 92 has a circular hole 94, a first substantially oval hole 96 and a second substantially oval hole 98, all having centers extending along an imaginary circle centered at the center of plate 92.

A circular plug conduit 100 is formed on the upper surface of circular plate 92 in surrounding relation to circular hole 94. Conduit 100 is open at its upper and lower ends and has an outside diameter and a height substantially equal to the inside diameter and height, respectively, of lower venturi conduit section 66 and an inside diameter equal to the inside diameter of upper venturi conduit section 68. Thus, when reservoir plug 90 is inserted within upper annular skirt section 28, plug conduit 100 fits snugly within lower venturi conduit section 66 and the inner surface of plug

upper end to a lower end thereof, to provide a venturi effect. In addition, the inner diameter of arcuate plug conduit 102′ may be greater than the inner diameter of upper chamber wall portion 52′. Further, to better ensure a smooth lower surface, a thin flat, circular metal plate 93′ of electropolished stainless steel is secured to the lower surface of reservoir plug 90′. In such case, plate 92′ has an opening 101′ of the same dimensions as arcuate plug conduit 102′, while oval holes 96′ and 98′ are provided in metal plate 93′. Of course, metal plate 93′ has a further circular opening 95′ coincident with circular hole 94′ of circular plate 92′. Preferably, metal plate 93′ is insert molded onto a plastic base material. The metal portion contacts dosing plate 180 in the assembled device, providing a very flat, smooth and rigid surface to prevent powder leakage from the reservoir. In addition, the metal dissipates any static electricity charges generated by friction between surfaces during dose loading operations, which charges can adversely affect powder flow into and out of the dosing station.

As shown in Figs. 14-21, driving body 120 includes a circular top wall 122 having an annular skirt 124 extending downwardly from the periphery of circular top wall 122.

Annular skirt 124 includes an upper annular skirt section 126 with its upper end extending downwardly from the periphery of circular top wall 122, and a lower annular skirt section 128 extending downwardly from the lower end of upper annular skirt section 126. Lower annular skirt section 128 has an inner and outer diameter greater than the inner and outer diameters, respectively, of upper annular skirt section 126. Accordingly, an inner annular shoulder 130 is formed at the lower edge of upper annular skirt section 126, along the inside of annular skirt 124. However, the outer surface of the transition area between upper

closes the upper open end of powder supply conduit 60 when reservoir body 22 is assembled with driving body 120. Therefore, powder 62 can only escape through manifold 46, opening 55 and substantially oval holes 96 and 98.

Further, a slightly inclined, curved retaining wall 148 extends downwardly from the lower surface of circular top wall 122 in partial surrounding relation to circular opening 142 to ensure a further separation between powder supply conduit 60 and frusto-conical venturi conduit 64 when reservoir body 22 and driving body 120 are assembled.

In order to provide for secondary air flow, as will be described hereinafter, the wall defining upper annular skirt section 126 extends inwardly in the radial direction to form a first outer air passage 150 adjacent to circular opening 142 in the circumferential direction of driving body 120 and a second outer air passage 152 having its center arcuately spaced approximately 100° from the center of first air passage 150.

Short, axially extending upper guide walls 154 and 156 are formed along a common circular arc spaced slightly inwardly from the periphery on the upper surface of circular top wall 122 in order to secure a nozzle to driving body 120, as will be described in greater detail hereinafter. Specifically, upper guide wall 154 is formed circumferentially along the larger arc between air passages 150 and 152; and upper guide wall 156 is formed circumferentially along the smaller arc between air passages 150 and 152. The common circular arc along which upper guide walls 154 and 156 extend is spaced slightly from the peripheral edge of circular top wall 122 so as to define an annular retaining ledge 159 on circular top wall 122, positioned outwardly of upper guide walls 154 and 156 in the radial direction.

metered dose hole 184 near the periphery thereof which functions as a single powder receptacle, that is, for holding a metered dose of powder 62. In order to prevent the metered dose of powder from falling through dose hole 184, a powder retainer 186 is formed in covering relation to the lower surface of disc 182, extending at least over dose hole 184. Preferably, powder retainer 186 is formed by a mesh screen, filter, porous material or the like which has a minimal restrictive effect on gas flow therethrough, while preventing appreciable loss of powdered medicament below the lower surface of disc 182. Powder retainer 186 can be fabricated from any suitable material, including cellulosics, polymerics, metals, ceramics, glasses or composites thereof, exemplary useful materials including sintered porous plastics, porous polymer membranes, natural or synthetic woven fabrics, nonwoven synthetic fabrics and the like. More specifically, useful materials include polyester and polyolefin woven mesh, and porous membranes of polyolefins, polycarbonates, poly-tetrafluoroethylene, polyvinylidene dichloride, and mixed esters of cellulose.

In this regard, metering dose plate 180 has a circular shallow recess 183 at the underside of thin disc 182. Shallow recess 183 is concentric with metered dose hole 184 but has a larger diameter than that of metered dose hole 184. Powder retainer 186 has a circular configuration with an outer diameter equal to the diameter of shallow recess 183 and is secured within shallow recess 183.

With such an arrangement, there is a problem in accurately positioning powder retainer 186 in shallow recess 183. Specifically, with a hot melt adhesive, the adhesive may leak into the mesh of powder retainer 186. Further, quality and consistency in positioning of powder retainer 186 therein cannot be obtained by

with a bar 190 extending axially along the inner surface of mounting post 188 in diametric relation to metered dose hole 184. Bar 190 extends from the lower surface of disc 182 to a position slightly spaced from the lower edge of mounting post 188, and preferably has a square cross-sectional configuration. As will be understood from the description hereinafter, bar 190 ensures that metering dose plate 180 will remain stationary with respect to powder housing 20 when powder housing 20, which includes reservoir body 22, reservoir plug 90 and driving body 120, is rotated.

In operation, metered dose hole 184 is initially in alignment with frusto-conical venturi conduit 64. As will be explained hereinafter, powder housing 20 is only permitted to rotate 180° relative to metering dose plate 180. During initial priming rotation, metered dose hole 184 passes under manifold 46 and substantially oval holes 96 and 98. As a result, powder 62 falls within and is scraped into metered dose hole 184. Specifically, the side walls defining substantially oval holes 96 and 98 function to scrape the powder 62 into metered dose hole 184. It will be appreciated that, since oval holes 96 and 98 are spaced less than 180° from circular hole 94, metered dose hole 184 travels completely past oval holes 96 and 98 and manifold 46. Then, during the return rotation back to the initial position, metered dose hole 184 passes back under manifold 46 and substantially oval holes 96 and 98, into alignment with venturi conduit 64. During this return travel, the side walls defining substantially oval holes 96 and 98 again function to scrape the powder 62 into metered dose hole 184, thus ensuring that metered dose hole 184 is completely and accurately filled. Thus, the scraping action is provided during both counterclockwise and clockwise rotation, that is, both during the 180° loading stage and the reverse 180° movement to the inhalation stage.

polyvinylidene dichloride, and mixed esters of cellulose.

However, unlike powder retainer 186 of metering dose plate 180, powder retainer 186' is formed along substantially the entire undersurface of disc 182', as shown best in Fig. 24B. Thus, there is no formation of a shallow recess 183 as in disc 182. In this regard, powder retainer 186' has an annular configuration with an outer diameter slightly smaller than the outer diameter of disc 182'.

In order to secure powder retainer 186' to the underside of disc 182', the underside of disc 182' is provided with a plurality of concentric ribs or spikes 185', each having a substantially inverted triangular cross-sectional configuration. With such arrangement, when the mesh screen of powder retainer 186' is positioned on the underside of disc 182', an ultrasonic welding operation is performed. Specifically, ultrasonic energy is directed toward the underside of disc 182'. In such case, the concentric spikes 185' function as energy directors which absorb greater amounts of energy than the remainder of the underside of disc 182'. As a result, the plastic material of spikes 185' is fused into the mesh to secure powder retainer 186' thereat. With this arrangement, there is a uniform energy that is applied for securing powder retainer 186', and an automated operation can be used to perform such securing operation, achieving a consistency at all times.

As with metering dose plate 180, metering dose plate 180' includes an annular mounting post 188' extending downwardly from the lower surface of disc 182' and centrally located thereon. Annular mounting post 188' is formed with a bar 190' extending axially along the inner surface of mounting post 188' in diametric relation to metered dose hole 184'. Bar 190' extends the entire height of mounting post 188', and

A cylindrical boss 216 is formed centrally and axially on the upper surface of circular top wall 202, with an upper annular portion 217 thereof partially cut-away and a radial segment 219 thereof also cut away. A coaxial retaining post 218 of lesser diameter than cylindrical boss 216 is formed at the upper end of cylindrical boss 216. Accordingly, an outer annular ledge 220 is formed at the upper edge of cylindrical boss 216. Retaining post 218 has an outer diameter slightly less than the inner diameter of annular mounting post 188 of metering dose plate 180. Retaining post 218 is formed with a slot 222 along the length thereof. Accordingly, due to bar 190 and slot 222, mounting post 188 of metering dose plate 180 is retained on retaining post 218 in a non-rotatable manner to ensure that metering dose plate 180 will remain stationary with respect to powder housing 20 when powder housing 20, which includes reservoir body 22, reservoir plug 90 and driving body 120, is rotated.

Two short stub walls 221 and 223 are formed on the upper surface of top wall 202, immediately on opposite sides of cylindrical boss 216. Stub walls 221 and 223 are angled with respect to each other at an angle of approximately 30 degrees.

As part of a counter mechanism which will be described in greater detail hereinafter, a first rotation prevention spring detent 224 is mounted in a cantilever manner on circular top wall 202. Specifically, a curved vertical detent supporting wall 226 extends upwardly from circular top wall 202 at a position substantially midway between annular ledge 206 and cylindrical boss 216, and first rotation prevention spring detent 224 extends from one edge 228 of detent supporting wall 226, parallel to and spaced above circular top wall 202. Further, the free end of first rotation prevention spring detent 224 is provided with an outward radially directed tab 230 thereat.

extends through annular boss 266 and central opening 264, the lower edge of annular boss 266 seats upon annular ledge 220.

An upper annular retaining lip 268 extends upwardly from the peripheral edge of disc 262. Further, two radially extending driven ears 270 and 272 are formed in diametrically opposite positions at the peripheral edge of annular lip 268. Ear 270 has a width substantially equal to the width of drive slot 34 of reservoir body 22 so as to fit therein and be driven thereby, and ear 272 has a width substantially equal to the width of drive slot 36 of reservoir body 22 so as to fit therein and be driven thereby.

Further, an arcuate pawl driving wall 274 extends from the lower surface of disc 262 between annular boss 266 and the periphery of disc 262, for an arcuate distance of approximately 79°. Pawl driving wall 274 includes opposite pawl driving ends 276 and 278, as will be described in greater detail hereinafter with reference to the counter mechanism.

The biasing assembly further includes a coil spring 290 having one end seated on the upper surface of disc 262 of lower spring retainer 260, and restrained thereon by annular retaining lip 268.

As shown in Figs. 3, 4 and 35-37, the biasing assembly further includes a support plate 300 which supports metering dose plate 180, functions as an upper spring retainer, biases metering dose plate 180 against the lower surface of thin circular plate 92 of reservoir plug 90, and permits suction through metered dose hole 184 only when metered dose hole 184 is in alignment with venturi conduit 64.

Specifically, support plate 300 is formed by a disc 302 having an annular retaining lip 304 extending downwardly from the peripheral edge of disc 302.

Two radially extending driven ears 306 and 308 are formed in diametrically opposite positions at the

there is no mesh powder retainer 186 at metered dose hole 184 to reduce air flow through metered dose hole 184.

As shown in Fig. 39, which is an alternative embodiment of the arrangement of Fig. 38, slot 312 in support plate 300 is angled at opposite sides thereof in a downwardly diverging manner. With such arrangement, the air flow cross-sectional area at the bottom of slot 312 can be made greater than four times the air flow cross-sectional area of metered dose hole 184.

It will be appreciated from the above description that metering dose plate 180 is held stationary on base 200, due to bar 190 and slot 222. Further, powder housing 20, comprised of reservoir body 22, reservoir plug 100 and driving body 120, is rotatably mounted with respect to base 200 and metering dose plate 180.

In addition, support plate 300 is biased into engagement with the lower surface of metering dose plate 180 so as to support the same. In the operation, radially extending slot 312 is in alignment with metered dose hole 184 only when metered dose hole 184 is in alignment with venturi conduit 64. Thus, any powder 62 within metered dose hole 184 when metered dose hole 184 is out of alignment with venturi conduit 64 is sandwiched in metered dose hole 184 by mesh powder retainer 186 and the upper surface of disc 302 of support plate 300 at its lower end, and by the lower surface of thin circular plate 92 of reservoir plug 90 at its upper end. As will be discussed in greater detail hereinafter, in the stored or inactive position of metered powder dose dispenser 10, metered dose hole 184 is primed, and is positioned diametrically opposite to radially extending slot 312. In such position, powder 62 within metered dose hole 184 is held between the upper surface of disc 302 of support plate 300 and the lower surface of thin circular plate 92 of

gripping and rotation of metered powder dose dispenser 10.

A rectangular opening 329 is formed in lower annular wall 322, substantially diametrically opposite to slot 326, and substantially centrally along the height of lower annular wall 322. Opening 329 is formed by a large inner opening portion 329a and a contiguous outer opening portion 329b of smaller dimensions, so as to form a rectangular shoulder 329c. A rectangular transparent plastic window 330 is fixed in opening 329 and includes a central window portion 330a which fits snugly within outer opening portion 329b and a large inner securing portion 330b of larger dimensions that fits within large inner opening portion 329a and is secured to rectangular shoulder 329c by an adhesive, welding or the like. Window 330 is used with the counter mechanism which will be described in greater detail hereinafter.

Adapter 320 further includes an upper annular wall 332 of a lesser diameter than lower annular wall 322, and connected to the upper end of lower annular wall 322 by an outer annular shoulder 334.

An annular biasing lip 338 is formed on the inner surface of upper annular wall 332. When adapter 320 is pushed down so as to lock adapter 320 onto base 200, as described above, annular biasing lip 338 seats on outer annular shoulder 32 of reservoir body 22, and thereby biases reservoir body 22 down against the force of coil spring 290. Accordingly, coil spring 290 is compressed so that a biasing force always forces support plate 300 into abutment with metering dose plate 180, and always forces metering dose plate 180 into abutment with reservoir plug 90. However, such biasing action still permits rotation of reservoir body 22 relative to adapter 320 and metering dose plate 180.

At the same time, this compression ensures that driven ears 270 and 306 will always be located within

Recesses 344 and 346 are shallower than recesses 340 and 342, and are oriented to be 90 degrees offset from recesses 340 and 342 such that recesses 340-346 are equiangularly arranged about upper annular wall 332. As will be made apparent from the discussion hereinafter, recesses 344 and 346 are intended to receive spring fingers 163 and 165 to lock the assembly in position after the cap has been removed.

As shown in the top view of Fig. 43, recesses 340, 342, 344 and 346 each have one side thereof with a bevel 345 toward the inside surface thereof, the purpose for which will become apparent hereinafter.

A double helical cam track 352 is formed on the outer surface of upper annular wall 332, the purpose for which will become apparent from the description which follows. As is apparent, the walls 353 that form double helical track 352 have a substantially square cross-section, the purpose for which will become apparent from the discussion hereinafter with respect to the cap. Further, the entry 351 to each cam track 352 is formed as a vertical drop zone before rotation can begin, thus ensuring accurate registry of the closure cap and thereby, accurate operation of dispenser 10, as shown best in Figs. 40, 89B and 89C.

Lastly, the lowermost walls 353 have a common lowermost surface that extends in a horizontal plane, and together with outer annular shoulder 334, form an annular groove 355 therebetween for seating an O-ring 357 therein. Such O-ring 357 provides a vapor seal.

In order to ensure that the powder is de-agglomerated and properly mixed with the suction air from the open upper end of upper venturi conduit section 68 of venturi conduit 64, a swirl nozzle 380, as shown in Figs. 46-50, is mounted to the upper end of reservoir body 22. Air which contains agglomerated powder particles flows from upper venturi conduit section 68 into the swirl nozzle. Mechanical

respectively, with a two degree adjustment clearance. Preferably, each spiked rib 393, 393, 394 and 396 has a tapered end with a substantially triangular cross-sectional configuration.

During an inhalation process, swirl nozzle 380 and the mouthpiece (discussed later) secured thereto might detach from driving body 120 and be swallowed. Therefore, in order to fixedly secure swirl nozzle 380 onto driving body 120, an ultrasonic welding operation is performed. Specifically, ultrasonic energy is directed toward spiked ribs 392, 393, 394 and 396. In such case, the spiked or sharp ends of ribs 392, 393, 394 and 396 function as energy directors which absorb greater amounts of energy. As a result, the plastic material of spiked ribs 392, 393, 394 and 396 is fused into the plastic material of recesses 158a-158d to secure swirl nozzle 380 on driving body 120, as shown in Fig. 50B. With this arrangement, there is a uniform energy that is applied for securing swirl nozzle 380, and an automatic operation can be used to perform such securing operation, achieving a consistency at all times.

It will be appreciated that, in such position, first and second outer air passages 150 and 152 extend inwardly of annular side wall 384 to supply secondary air flow thereto which mixes with the air/powder mixture from venturi conduit 64 which is also supplied to the interior of annular side wall 384.

Circular top wall 382 has a central opening 402, and a supply chimney 404 is formed on the upper surface of circular top wall 384 in surrounding relation to central opening 402.

In order to break up the powder agglomerates, prior to supplying the same through supply chimney 404, a curved spiral-like wall 406 extends downwardly from circular top wall 382 and is connected at one end 408 to annular side wall 384. Specifically, curved wall

the powder agglomerates travel with sufficient velocity, there will be sufficient kinetic energy to break up the agglomerates.

Further, rather than providing a merely helical path along the axial direction of a nozzle, as in the prior art, curved wall 406 and, particularly, swirl cavity 412, first changes the direction of powder 62 from an axial direction of venturi conduit 64 to a transverse direction substantially perpendicular to the axial direction. In this transverse direction, powder 62 is then forced to continuously change direction in the transverse direction of swirl cavity 412. Upon exiting swirl cavity 412, the direction of powder 62 is again changed to an axial direction through supply chimney 404, while retaining a swirl component of the flow, that is, while swirling spirally through chimney 404. Since the micronized powder and any remaining agglomerates maintain the swirl imparted thereto from swirl cavity 412, the swirling flow applies a centrifugal force to the micronized powder and remaining agglomerates, creating additional impacts in supply chimney 404 so as to result in further breaking up of the remaining agglomerates.

Most of the agglomerate break-up should take place, however, in swirl cavity 412. The velocity attained by an agglomerate depends on the drag or suction force, the inertia of the agglomerate, and the length of swirl cavity 412, that is, the time the drag force acts on the agglomerate. Because of its inertia, the agglomerate impacts a wall in swirl cavity 412 to convert the same to micronized powder.

In addition, with the present invention, chimney 404 is provided with vertically oriented grooves or flutes 405 extending along the inner wall thereof. Flutes 405 provide more surfaces against which the agglomerates can impact against. Flutes 405 are shown as being formed by six vertical concave wall sections

dose hole 184. The pressure drop through swirl nozzle 380 can be changed by varying the angle between end 410 and the position where the first and second sections of curved wall 406 meet, that is, where the second section leaves central opening 402, as shown in Fig. 47. In a presently preferred embodiment, this angle is about 165°, although this value may change depending upon the required pressure drop.

Further, an annular mouthpiece securing wall 418 is formed on the upper surface of circular top wall 382, spaced slightly inwardly from the peripheral edge thereof. As a result, an annular ledge 420 is formed on the upper surface of circular top wall 382, outwardly of annular mouthpiece securing wall 418. Further, an annular lip 422 extends outwardly in the radial direction from the upper end of annular mouthpiece securing wall 418.

Also, gear teeth 424 are provided on the upper edge of annular mouthpiece securing wall 418. Although forty gear teeth are shown, the present invention is not so limited.

Finally, a locator tab 426 is provided on the upper surface of circular top wall 382, along the inner surface of gear teeth 424, diametrically opposite the location of venturi conduit 64 in the final assembled condition of the inhaler.

A mouthpiece 440, as shown in Figs. 3, 4 and 51-55, is secured to the upper end of swirl nozzle 380. Mouthpiece 440 includes a generally rectangular top wall 442 with an annular side wall 444 depending downwardly from the periphery of top wall 442. Because top wall 442 has a generally rectangular configuration and because of the annular configuration of side wall 444, upper portions at opposite sides 446 and 448 of side wall 444 corresponding to the lengthwise sides of top wall 442 slope upwardly in a diverging manner toward each other. The lips of a user of the device

elongated annular covering wall 522 which is closed at its upper end by a generally circular top wall 524. A lower annular securing skirt 526 of a larger diameter than annular covering wall 522, is secured to the lower end of annular covering wall 522 through an annular frusto-conical connector 528. The lower end of annular securing skirt 526 is open. Further, the inner diameter of lower annular securing skirt 526 is slightly larger than the outer diameter of upper annular wall 332 of adapter 320 so as to fit thereover.

In order to secure closure cap 520 onto metered powder dose dispenser 10, and particularly, in covering relation to mouthpiece 440, two helix cams 530 are formed in diametrically opposite relation on the inner surface of lower annular securing skirt 526. Thus, when closure cap 520 is inserted over powder housing 20, swirl nozzle 380 and mouthpiece 440, cams 530 of closure cap 520 initially vertically drop in entry 351 and then threadedly engage with double helical cam track 352 of adapter 320, until the lower edge of lower annular securing skirt 526 seats on the annular frusto-conical connecting section 334 of adapter 320.

It is noted that cams 530 and cam track 352 are provided in place of conventional screw threads. This is because, with conventional screw threads, cap 520 may be prematurely pulled off due to the tolerance of the threads. As a result, metered powder dose dispenser 10 may not be operated correctly, that is, not turned a full 180° during priming and delivery thereof. However, with cams 530 and cam track 352 having walls 353 of a square cross-section, numerous advantages are achieved, including preventing premature opening of cap 520, ease of use, ensuring proper location at all times of the rotational positions of the parts of dispenser 10, and ensuring that the counter (described hereinafter) is always correctly activated to always correctly change the dose count.

When closure cap 520 is removed from metered powder dose dispenser 10, metered dose hole 184 is in alignment with venturi conduit 64, ready for inhalation by the user. Thus, dispenser 10 is fully primed and ready for inhalation by a person. At such time, spring fingers 163 and 165 are positioned in recesses 344 and 346 of adapter 320. Thus, dispenser 10 is locked in this position.

The operation of inserting closure cap 520 is shown in Figs. 89A-89E and Figs. 90A and 90E. After the inhalation operation, closure cap 520 is positioned on the assembly, as shown in Fig. 89A. At this time, cams 530 are not engaged within cam tracks 352. Upon turning of closure cap 520, cams 530 fall within the beginning portions of cam tracks 352 and can be pushed down therein, as shown in Fig. 89B and 89C. At this time, priming ribs 534 and 536 engage and push in spring fingers 163 and 165, and also engage sides of driving recesses 164 and 166. In other words, during the initial closure operation, lower ramp portions 535 of priming ribs 534 and 536 engage upper portions of spring fingers 163 and 165 and bias the same inwardly of driving recesses 344 and 346. This is shown in more detail in Fig. 90A. As a result, driving body 120 can rotate relative to adapter 320 to the closed position, as shown in Figs. 89D and 89E. During this time, cap 520 engages with driving body 120, so that continued turning of cap 520 results in turning of driving body 120 relative to adapter 320. As cap 520 is rotated, it is pulled down by cams 530 riding in cam tracks 352.

At the completion of the rotation, and because of the configuration of spring fingers 163 and 165 and the complementary configuration of priming ribs 534 and 536, spring fingers 163 and 165 spring back into a locking position into mating engagement with priming ribs 534 and 536, 180° offset from the inhalation position, that is, with spring fingers 163 and 165

portions of spring fingers 163 and 165 and bias the same inwardly of recesses 344 and 346. Accordingly, driving body 120 can rotate relative to adapter 320 to the open position.

This results in opposite rotation of driving body 120, and thereby of venturi conduit 64 relative to metered dose hole 184, to a position in alignment. Thus, as soon as closure cap 520 is removed, metered dose hole 184, which is filled with powder 62, is in alignment with venturi conduit 64, and ready for inhalation. There is thus no need to provide any additional priming and set-up operation after closure cap 520 is removed.

Further, closure cap 520 includes six equiangularly spaced protrusions 538 formed at the inner surface of covering wall 522, spaced a small distance from top wall 524.

To protect powder 62 against moisture contamination, a desiccant holder 560 is held by protrusions 538 within closure cap 520. As shown in Figs. 64-66, desiccant holder 560 includes a circular top wall 562 and an annular side wall 564 extending down from the periphery thereof. An annular recess 566 is formed in the inner surface of annular side wall 564 at the lower end thereof for receiving a disc (not shown) which holds a desiccant, such as silica gel, therein. An annular rib 568 is formed on the outer surface of annular side wall 564. In this manner, desiccant holder 560 is inserted within closure cap 520. Due to the resilience of the plastic pieces, annular rib 568 rides over protrusions 538, so that desiccant holder 560 is held within closure cap 520 adjacent top wall 524 thereof. A slight modification to desiccant holder 560 is shown in the assembled view of Fig. 4.

A counter mechanism 580 is provided for counting the number of doses that have been dispensed or

lower annular lip 596. Specifically, two successive sets of numbers "0" through "9" are printed equiangularly thereabout. Numerical indicia 600 are printed in a vertical manner. Thus, indicia 600 can be read while metered powder dose dispenser 10 is upright, that is, in the manner that it should be used.

Twenty gear teeth 602 are equiangularly formed on the inner surface of disc 592 in correspondence with the twenty numbers of numerical indicia 600. All gear teeth 602 have the same depth in the radial direction, with the exception that diametrically opposite gear teeth 604 and 606 of gear teeth 602, corresponding to the opposite numbers "5" of numerical indicia 600, are deeper than the remaining gear teeth 602, that is, gear teeth 604 and 606 extend outwardly in the radial direction to a greater extent than the remaining gear teeth 602. When continuous counter ring 590 is seated on base 200, first rotation prevention spring detent 224 of base 200 engages with one gear tooth 602 at a time, to prevent clockwise rotation of continuous counter ring 590 on base 200.

As shown in Figs. 3, 4 and 71-74, intermittent counter ring 620 is formed by a disc 622 having a wall with a substantially rectangular cross-section. A lower annular lip 624 axially extends from the lower, outer edge of disc 622, as a smooth extension of disc 622, but of a lesser cross-sectional width. As a result, an inner annular ledge 626 is formed at the lower edge of disc 622. In this regard, intermittent counter ring 620 can be rotatably seated on continuous counter ring 590, and in particular, inner annular ledge 626 is spaced above continuous counter ring 590, while lower annular lip 624 seats on outer annular ledge 594 of continuous counter ring 590.

A plurality of numerical indicia 628 are printed on the smooth combined outer surface of disc 622 and lower annular lip 624. Specifically, numbers "0"

After the next nine doses, only continuous counter ring 590 rotates one increment at a time for each dose. After the number "190" is exposed through window 330, the next dose results in both continuous counter ring 590 and intermittent counter ring 620 rotating to form the number "189". This operation continues until the number "00" is exposed through window 330. At this time, intermittent counter ring 620 has been rotated to a position so that dose limiting tab 632 abuts against dosage limiter tab 336 of adapter 320, to prevent further relative rotation of powder housing 20 with respect to metering dose plate 180.

In order to cause such rotation of continuous counter ring 590 and intermittent counter ring 620, spring-biased pawl assembly 640 includes a pawl driver 642, as shown in Figs. 3, 4 and 75-79. Pawl driver 642 includes an arcuate outer wall 644 having a height greater than the combined height of continuous counter ring 590 and intermittent counter ring 620. A U-shaped retainer 650 is connected to the free ends of arcuate wall 644. U-shaped retainer 650 has a height less than that of arcuate wall 644. Accordingly, a loop defining an open area 652, is formed by arcuate wall 644 and U-shaped retainer 650. A flange 648 of a substantially triangular cross-sectional configuration, forms an extension at one side of arcuate wall 644 at the intersection thereof with U-shaped retainer 650, but being of a height substantially equal to that of U-shaped retainer 650.

A pawl 654 is centrally formed on the outer or convex surface of arcuate wall 644. Thus, when pawl driver 642 is inserted on circular top wall 202 of base 200 in surrounding relation to cylindrical boss 216, pawl 654 can be inserted within a gear tooth 602. However, because gear teeth 630 extend along a larger diameter circle than gear teeth 602, pawl 654 can only engage with gear teeth 602 and not with gear teeth 630.

75-79 are identified by the same reference numerals, with a prime (′) added thereto.

The only difference between pawl assembly 640′ and pawl assembly 640 is that the free end of spring 658′ of pawl assembly 640′ has a slight convex curvature away from the fixed end thereof.

Referring to Figs. 84-88, there is shown a spring-biased pawl assembly 640" according to still another embodiment of the present invention, in which elements corresponding to those of pawl assembly 640 of Figs. 75-79 are identified by the same reference numerals, with a double prime (") added thereto.

One difference between pawl assembly 640" and pawl assembly 640 is that spring 658" of pawl assembly 640", rather than being formed as a substantially L-shaped member, is formed is a generally linear member with tapered sides, extending at an angle from the upper end of the inner surface of arcuate wall 644". Another difference is that flange 648 is eliminated entirely.

In the operation of counter mechanism 580, lower spring retainer 260 rotates 180° with reservoir body 22 relative to metering dose plate 180 between the stored position when closure cap 520 is threaded onto adapter 320 and the inhalation position when closure cap 520 is removed from adapter 320. When metered powder dose dispenser 10 is in the stored position, pawl 654 is engaged within a shallow gear tooth 602 of continuous counter ring 590, and therefore, does not engage with a gear tooth 630. Further, in such position, pawl driving end 276 of arcuate pawl driving wall 274 engages with pawl assembly 640.

When reservoir body 22 is rotated the first 178° toward the inhalation position, pawl driving end 278 of arcuate pawl driving wall 274 is rotated into engagement with the opposite side of pawl assembly 640. As a result, pawl 654 is rotated so that it rides out of the shallow gear tooth 602, thereby compressing

driving wall 274 would be changed to incrementally drive pawl assembly 640.

Accordingly, with the present invention, a metered powder dose dispenser 10 is provided that accurately measures the doses of powdered medicament to be delivered to the patient. Specifically, dispenser 10 is greatly simplified in construction and assembly over the prior art.

All of the above elements, with the exception of metal plate 93′ and spring 290, are preferably fabricated from readily available plastics, while the former parts are preferably fabricated from suitable metals. Typically, the various components which do not require porosity or other special properties will be molded from one or more thermoplastic substances having the desired rigidity and strength. In some embodiments, the component containing the powder receptacle is relatively thin and, to maintain a required degree of surface flatness, will be constructed from a less easily deformed substance such as a reinforced plastic, ceramic or metal. Of course, materials selected must be chemically compatible with the medication to be dispensed. For reasons of cost, a maximum utilization of plastics will be preferred where the device is intended to be disposable with no, or only a limited number of, medicament refills after the initial charge has been dispensed. Other "composite" components can be used elsewhere in the device where special properties are required.

In order to assemble metered powder dose dispenser 10, powder housing 20 is first assembled. Specifically, reservoir plug 90 is inserted within reservoir body 22, desiccant holder 560 is snapped into closure cap 520, swirl nozzle 380 is assembled with driving body 120 and mouthpiece 440 is assembled with swirl nozzle 380. Next, continuous counter ring 590 is fit onto base 200 and intermittent counter ring 620 is

support plate 260, such that narrow driven ears 270 and 306 fit within narrow drive slot 34, and wider driven ears 272 and 308 fit within wider drive slot 36 of reservoir body 22. In such case, venturi conduit 64 is in alignment with metered dose hole 184. In order to assemble the above parts together, adapter 320 is then placed over the above assembly such that slot 326 thereof is in alignment with post 214 of base 200. Adapter 320 is then pressed down until annular ledge 210 of base 200 snaps into annular groove 324 of adapter 320. At this time, coil spring 290 is compressed, the number "199" appears through window 330 of adapter 320, and recesses 340 and 342 of adapter 320 are in alignment with drive slots 34 and 36, respectively, of reservoir body 22.

Thereafter, powder supply conduit 60 is filled through the upper open end thereof. Then, driving body 120, with nozzle 380 and mouthpiece 440 thereon, is fit over reservoir body 22, such that circular plug conduit 144 of driving body 120 plugs the upper open end of powder supply conduit 60 and such that the upper open end of venturi conduit 64 extends through circular opening 142 in driving body 120. In this position, the lower edge of lower annular skirt section 128 of driving body 120 is positioned immediately above the upper edge of upper annular wall 332 of adapter 320.

Closure cap 520 is then threaded onto adapter 320, whereby powder housing 20 is rotated 180° relative to metering dose plate 180 so as to prime metered powder dose dispenser 10, that is, so as to scrape powder 62 into metered dose hole 184. This moves pawl 654 to the next gear tooth 602.

When a user desires to inhale a dosage of the powder 62, closure cap 520 is unthreaded and removed, thereby rotating powder housing 20 back 180° so as to align venturi conduit 64 with metered dose hole 184, ready for inhalation. At this time, pawl 654 is

WHAT IS CLAIMED IS:

1. A powder dispenser comprising:

supply means for holding a supply of powdered material to be dispensed;

an inhalation conduit extending in a first direction and positioned in displaced relation to said supply means;

means for carrying a predetermined amount of said powdered material from said supply means to said inhalation conduit; and

a nozzle for reducing particle sizes of agglomerates of powdered material from the inhalation conduit to form micronized powdered material and for mixing said micronized powdered material with suction air, said nozzle including:

cavity means for changing the direction of flow of said powder from said first direction of said inhalation conduit to a second direction different from said first direction, said cavity means being defined by a top wall and a skirt connected to a periphery of said top wall, said top wall having an opening therein;

swirl means for substantially continuously changing the direction of flow of said powder in said second direction in said cavity means; and

chimney means extending from said top wall in surrounding relation to said opening for changing the direction of flow of said powder from said second direction of said cavity means substantially back to said first direction, said chimney means extending along an axial direction thereof and including an inner tubular wall surface having irregularities extending in said axial direction.

2. The powder dispenser according to claim 1, wherein said irregularities are formed by a plurality of flutes on said inner tubular wall surface.

means including an inhalation conduit extending therethrough in a first direction, in displaced relation to said supply of powdered material, said powder housing means including:

a reservoir body including said supply of powdered material and said inhalation conduit, and

a driving body secured to said reservoir body for driving said reservoir body in a rotational direction, said driving body including a plurality of recesses in an upper portion thereof;

metering plate means for holding a metered amount of said powdered material, said metering plate means including metered dose hole means for holding said metered amount of said powdered material, said metering plate means being positionable below said supply of powdered material, and said metering plate means and said powder housing means being relatively bi-directionally rotatable with respect to each other about a common central axis so that said metered dose hole means can be placed in fluid communication selectively with said supply of powdered material or said inhalation conduit;

spring means for biasing said metering plate means and said powder housing means toward each other; and

nozzle means mounted to said driving body for receiving said metered amount of said powdered material through said inhalation conduit, said nozzle means including rib means welded in said recesses of said driving body.

10. A powder dispenser according to claim 9, wherein said driving body has a top wall, and said recesses are arranged along a peripheral portion of said top wall.

11. A powder dispenser according to claim 10, wherein said top wall has a circular configuration, and said

directionally rotatable with respect to each other about a common central axis so that said metered dose hole means can be placed in fluid communication selectively with said supply of powdered material or said inhalation conduit;

spring means for biasing said metering plate means and said powder housing means toward each other;

an adapter non-rotatably mounted with respect to said metering plate means, said adapter including at least one locking recess for receiving said at least one spring finger therein to prevent rotation of said powder housing means relative to said adapter and said metering plate means; and

closure cap means for covering said powder housing means and for priming said powder dispenser for use, said closure cap means including priming means for rotating said powder housing means such that said inhalation conduit is in communication with said metered dose hole means when said closure cap means is removed from covering relation of said powder housing means and for rotating said powder housing means such that said inhalation conduit is out of communication with said metered dose hole means when said closure cap means is secured in covering relation to said powder housing means, said priming means including at least one priming rib for biasing said at least one spring finger out of said at least one locking recess of said adapter to enable rotation of said powder housing means relative to said metering plate means and for engaging with said at least one driving recess to rotate said powder housing means relative to said metering plate means.

15. The powder dispenser according to claim 14, wherein said driving body includes two diametrically opposite spring fingers, said adapter includes two diametrically opposite locking recesses and said cap

metered amount of said powdered material, said metering plate means being positionable below said supply of powdered material, and said metering plate means and said powder housing means being relatively bi-directionally rotatable with respect to each other about a common central axis so that said metered dose hole means can be placed in fluid communication selectively with said supply of powdered material or said inhalation conduit;

spring means for biasing said metering plate means and said powder housing means toward each other;

an adapter non-rotatably mounted with respect to said metering plate means, said adapter including at least one helical cam track having a substantially square cross-sectional configuration; and

closure cap means for covering said powder housing means and for priming said powder dispenser for use, said closure cap means including priming means for rotating said powder housing means such that said inhalation conduit is in communication with said metered dose hole means when said closure cap means is removed from covering relation of said powder housing means and for rotating said powder housing means such that said inhalation conduit is out of communication with said metered dose hole means when said closure cap means is secured in covering relation to said powder housing means, said closure cap means including:

an annular skirt having an inner surface, and

at least one cam formed on a lower portion of the inner surface of annular skirt for riding within said at least one helical cam track.

20. The powder dispenser according to claim 19, wherein each said cam track includes an entry portion defining a vertical drop zone in which said at least one cam engages prior to permitting helical movement of

said retainer means being welded to said ribs such that said ribs are fused into said retainer means.

23. The powder dispenser according to claim 22, wherein said retainer means is formed by a material selected from the group consisting of a gas-permeable filter, a mesh screen, a porous material mesh and a perforated plate element.

24. The powder dispenser according to claim 22, wherein said retainer means is ultrasonically welded to said ribs.

25. The powder dispenser according to claim 22, wherein said ribs are formed in a plurality of spaced apart, concentric circles.

26. The powder dispenser according to claim 22, wherein each rib has a substantially triangular cross-sectional configuration.

27. A method of forming a metering plate and a gas permeable retainer thereon, for use in a powder dispenser, comprising the steps of:

positioning the gas permeable retainer at a predetermined position in a first mold half used for injection molding said metering plate;

positioning a second mold half adjacent said first mold half to form a molding chamber therebetween used for injection molding said metering plate, said second mold half having a through opening therein in alignment with said retainer at said predetermined position in said first mold half;

inserting a core pin through said through opening in said second mold half into engagement with said retainer to hold the retainer in position against

spring means for biasing said metering plate means and said powder housing means toward each other;

a base having an axially extending retaining post thereon coaxial with said common axis and non-rotatably connected with said metering plate means; and

counter means, rotatably mounted on said base in surrounding relation to said retaining post, for providing a visual count of the number of doses of said powdered material that have been dispensed or remain to be dispensed in response to said relative rotation of said powder housing means and said metering plate means, said counter means including:

counter ring means for providing said visual count, said counter ring means being rotatable about said common central axis and having counting indicia thereon for displaying said visual count, said counter ring means including:

a continuous counter ring having counting indicia thereon and gear teeth formed therearound on an inner surface thereof, and

an intermittent counter ring coaxially mounted with said continuous counter ring and having counting indicia thereon and gear teeth formed therearound on an inner surface thereof,

display means through which one of said counting indicia from said counter ring means is displayed to indicate a count corresponding to a number of doses of powdered material that have been dispensed or remain to be dispensed; and

actuating means for incrementally rotating said counter ring means in response to said relative rotation between said metering plate means and said powder housing means, said actuating means including pawl means engaging with said gear teeth of said continuous counter ring and said intermittent counter ring for rotating said continuous counter ring one increment each time that a dose of the powdered

33. The powder dispenser according to claim 29, wherein said gear teeth of said continuous counter ring are arranged in correspondence with said counting indicia thereon, and said gear teeth of said intermittent counter ring are arranged in correspondence with said counting indicia thereon.

34. The powder dispenser according to claim 29, wherein the gear teeth of said continuous counter ring include a plurality of successive first gear teeth of a first depth and at least one second gear tooth of a second, greater depth, each said second gear tooth being positioned after every predetermined number of said first gear teeth; and said intermittent counter ring includes a plurality of successive third gear teeth of a depth equal to the depth of each said second gear tooth of said continuous counter ring so that said pawl engages with successive ones of said first gear teeth during successive dosing operations and engages with one said second gear tooth and a third gear tooth of said intermittent counter ring after a plurality of the dosing operations.

35. The powder dispenser according to claim 29, wherein said actuating means further includes pawl driver means for incrementally rotating said pawl means, said pawl driver means including a retainer rotatably mounted on said base coaxially with said continuous counter ring and said intermittent counter ring, said retainer including first pawl driver means for engaging with one side of said pawl means to incrementally rotate said pawl means in a first rotational direction at the end of rotation of said retainer in said first rotational direction and second pawl driver means for engaging an opposite side of said pawl means to incrementally rotate said pawl means in a second, opposite rotational direction at the end of

said inhalation conduit, said metering plate means having an underside with ribs thereon;

gas permeable retainer means for retaining a dose of said powdered material in said metered dose hole means, said retainer means being positioned below said metered dose hole means and in overlying relation to the underside of said metering plate means and to said ribs thereon, said retainer means being welded to said ribs such that said ribs are fused into said retainer means;

spring means for biasing said metering plate means and said powder housing means toward each other;

nozzle means, mounted to said driving body, for reducing particle sizes of agglomerates of powdered material from an inhalation conduit extending in a first direction in a powder dispenser to form micronized powdered material and for mixing said micronized powdered material with suction air, said nozzle means comprising:

cavity means for changing the direction of flow of said powder from said first direction of said inhalation conduit to a second direction different from said first direction, said cavity means being defined by a top wall and a skirt connected to a periphery of said top wall, said top wall having an opening therein,

swirl means for substantially continuously changing the direction of flow of said powder in said second direction in said cavity means,

chimney means extending from said top wall in surrounding relation to said opening for changing the direction of flow of said powder from said second direction of said cavity means substantially back to said first direction, said chimney means extending along an axial direction thereof and including an inner tubular wall surface having irregularities extending in said axial direction, and

counter means, rotatably mounted on said base in surrounding relation to said retaining post, for providing a visual count of the number of doses of said powdered material that have been dispensed or remain to be dispensed in response to said relative rotation of said powder housing means and said metering plate means, said counter means including:

counter ring means for providing said visual count, said counter ring means being rotatable about said common central axis and having counting indicia thereon for displaying said visual count, said counter ring means including:

a continuous counter ring having counting indicia thereon and gear teeth formed therearound on an inner surface thereof, and

an intermittent counter ring coaxially mounted with said continuous counter ring and having counting indicia thereon and gear teeth formed therearound on an inner surface thereof,

display means through which one of said counting indicia from said counter ring means is displayed to indicate a count corresponding to a number of doses of powdered material that have been dispensed or remain to be dispensed; and

actuating means for incrementally rotating said counter ring means in response to said relative rotation between said metering plate means and said powder housing means, said actuating means including pawl means engaging with said gear teeth of said continuous counter ring and said intermittent counter ring for rotating said continuous counter ring one increment each time that a dose of the powdered material is dispensed to display another one of said counting indicia of said continuous counter ring through said display means, and for rotating said intermittent counter ring one increment every predetermined number of rotational increments of said

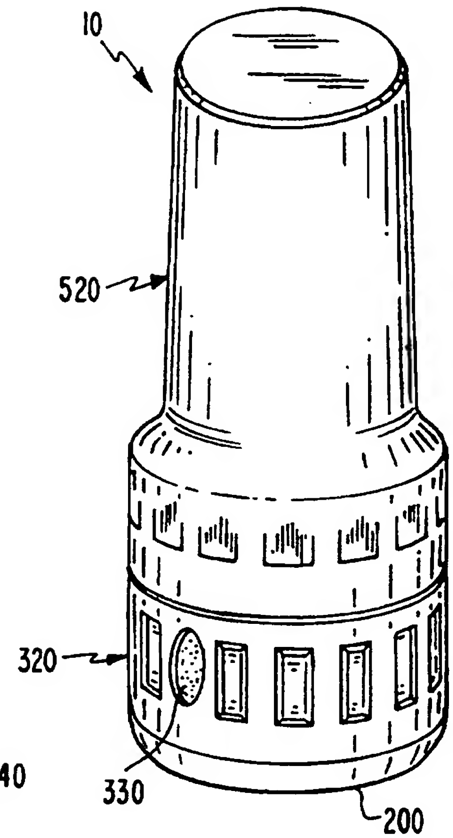


FIG. 1

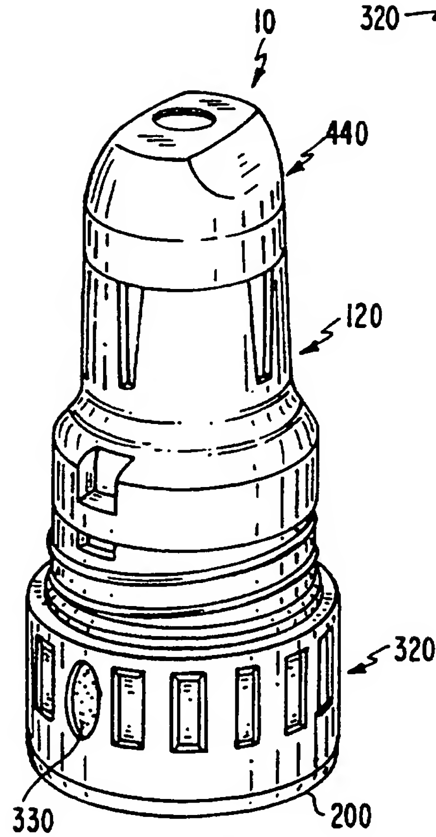


FIG. 2

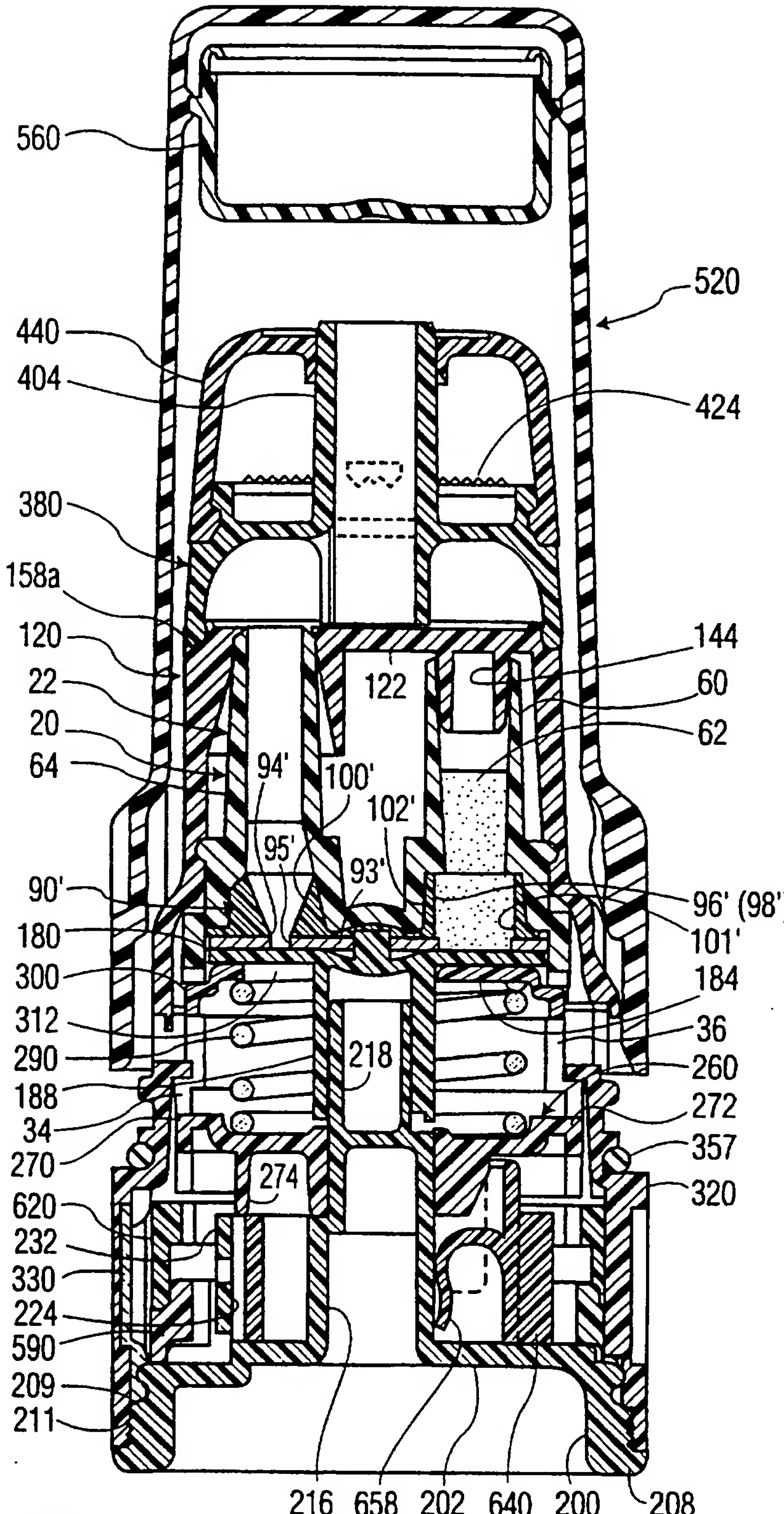

560
520
440
404
424
380
158a
120
22
20
64
144
122
60
62
94'
100'
102'
95'
93'
90'
180
96' (98')
101'
300
312
290
188
34
270
184
36
218
260
272
357
274
320
620
232
330
224
590
209
211
216
658
202
640
200
208

FIG. 4

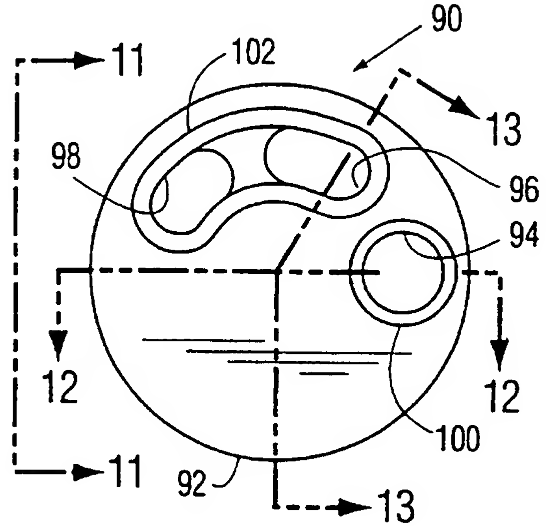


FIG. 9

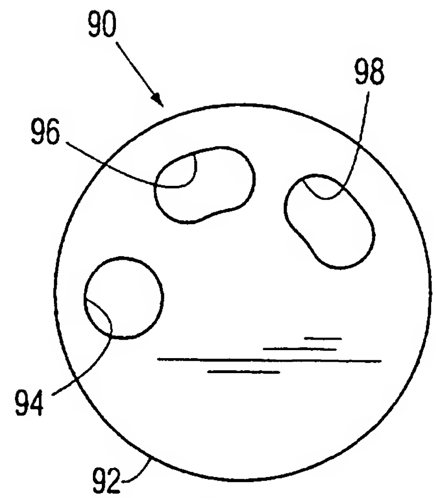


FIG. 10

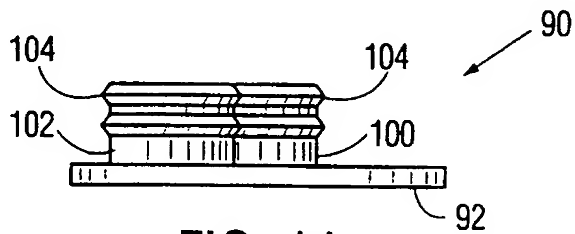


FIG. 11

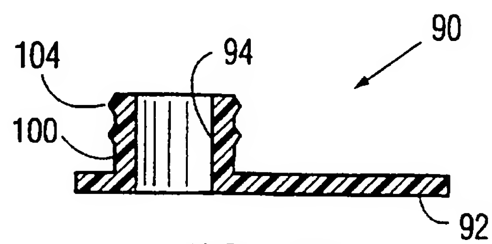


FIG. 12

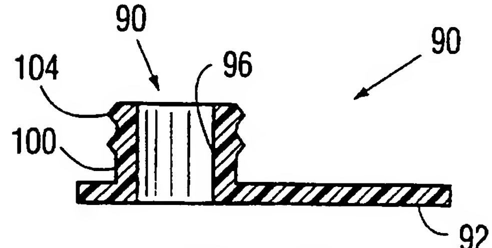


FIG. 13

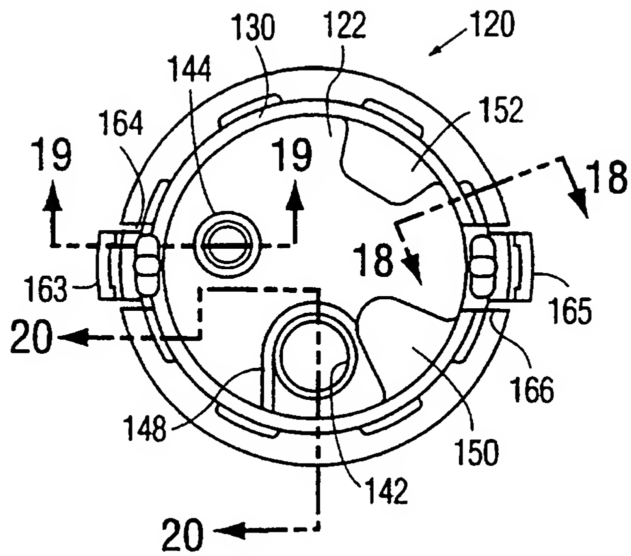

130
122
120
144
152
164
19
19
18
18
163
165
20
166
148
150
142
20

FIG. 16

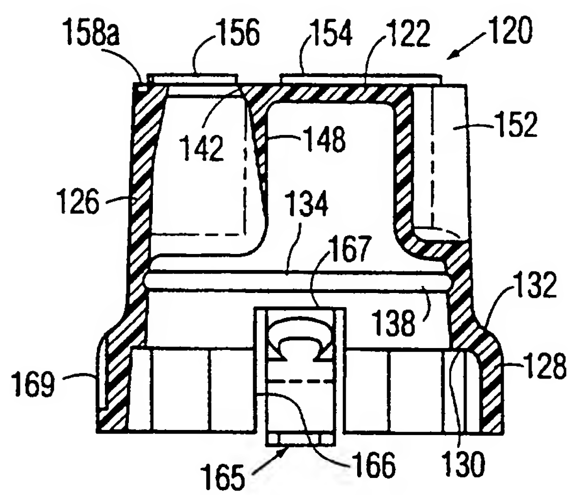

158a
156
154
122
120
142
148
152
126
134
167
132
138
169
128
165
166
130

FIG. 17

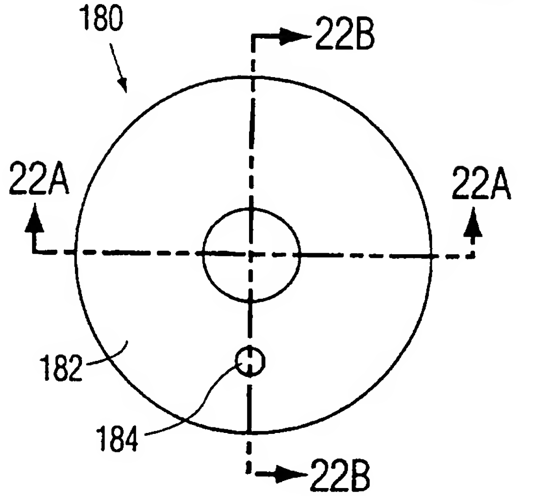


FIG. 22

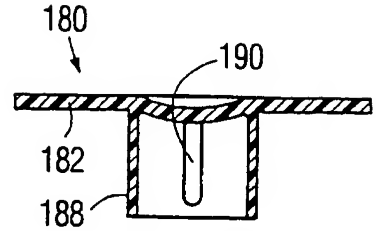


FIG. 22A

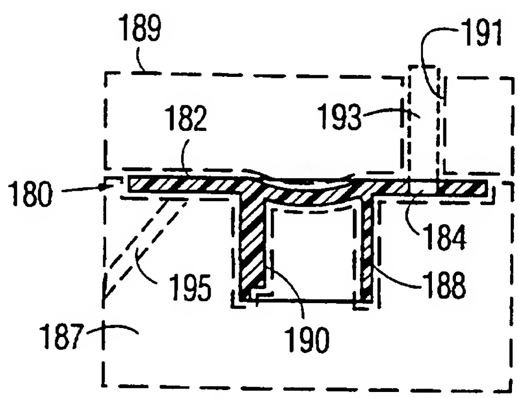


FIG. 22B

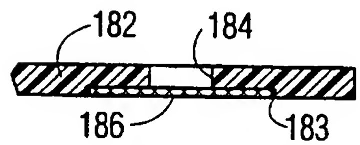


FIG. 22C

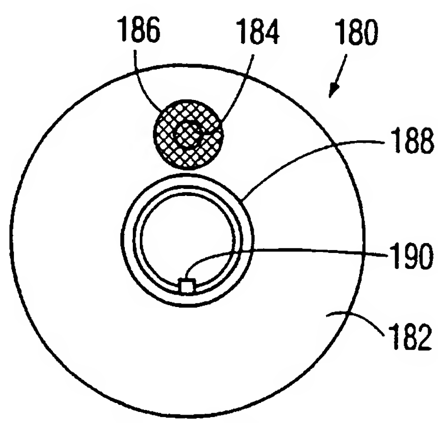


FIG. 23

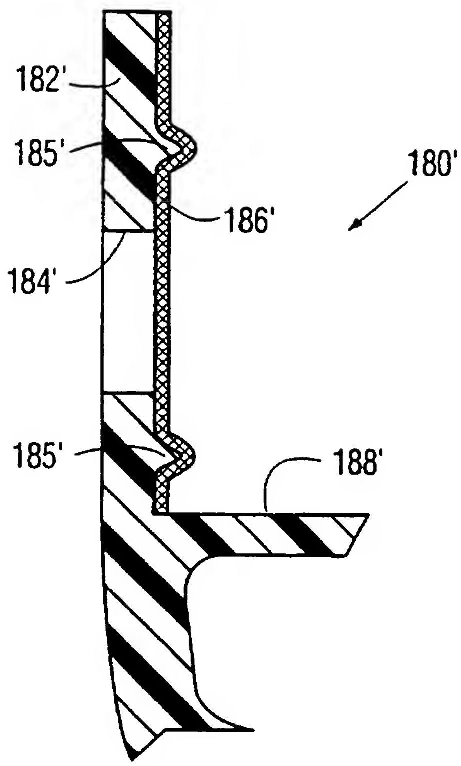


FIG. 24E

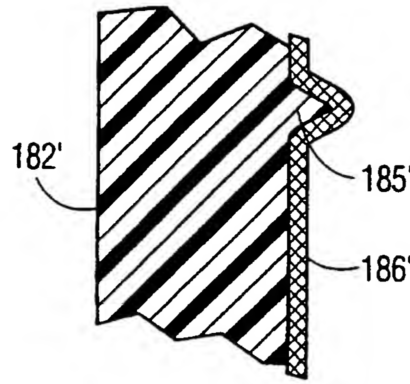


FIG. 24F

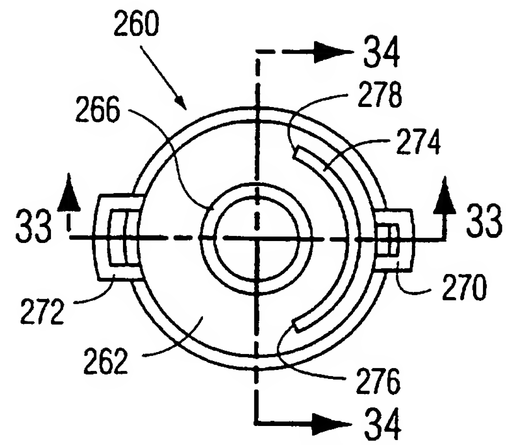


FIG. 30

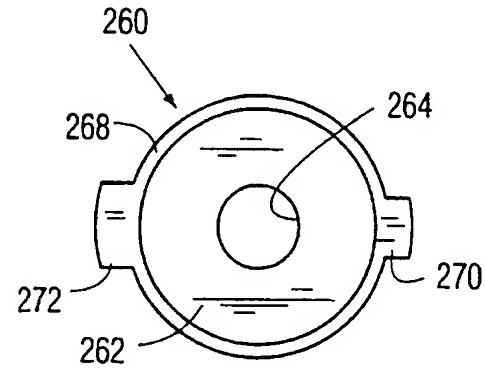


FIG. 31

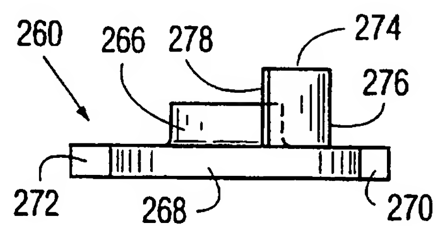


FIG. 32

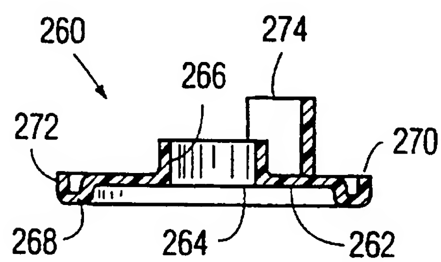


FIG. 33

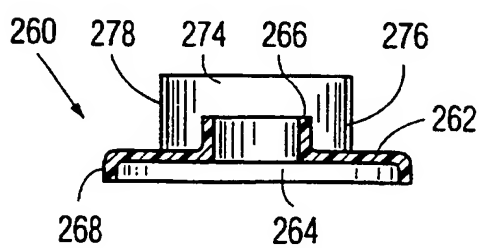


FIG. 34

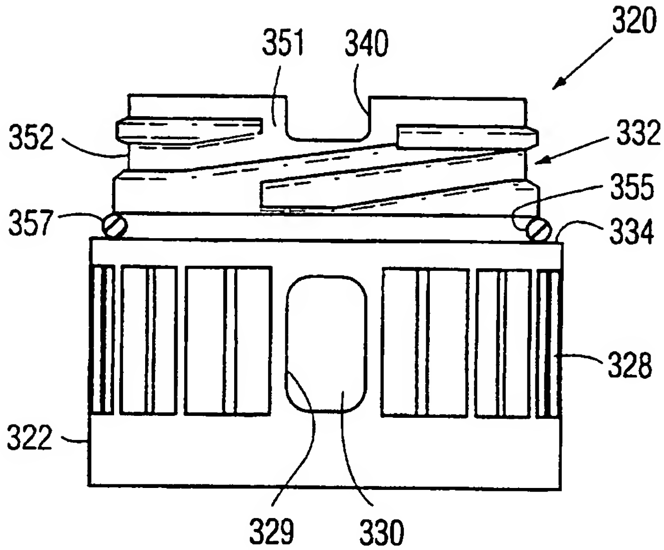

320
351
340
352
332
355
357
334
328
322
329
330

FIG. 40

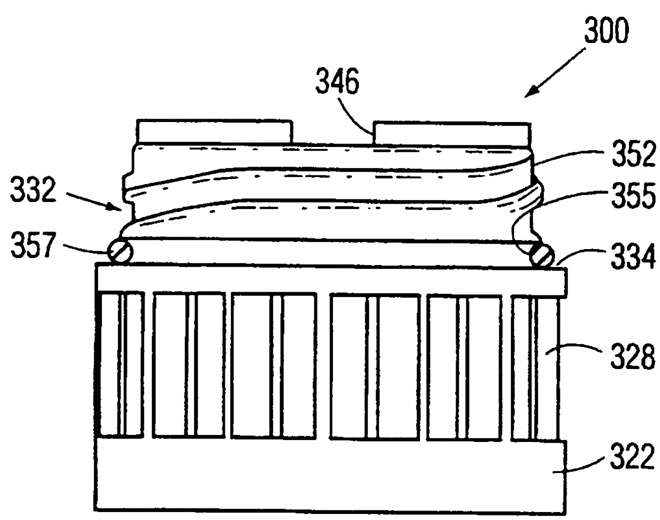

300
346
352
332
355
357
334
328
322

FIG. 41

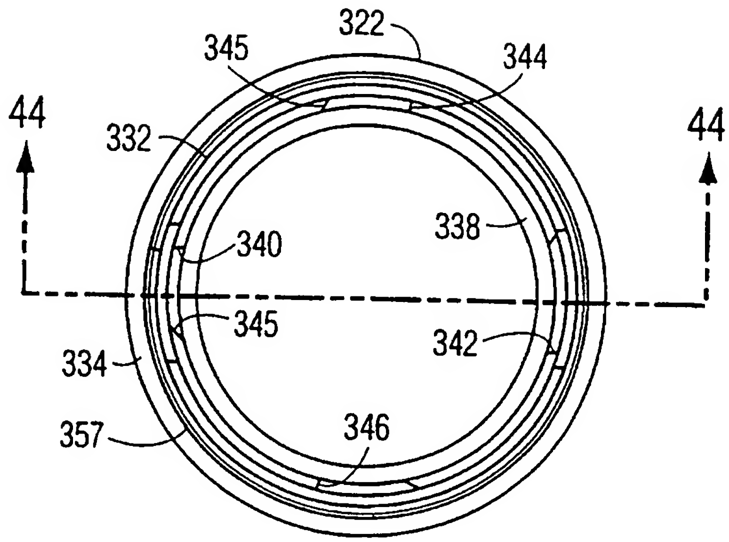


FIG. 43

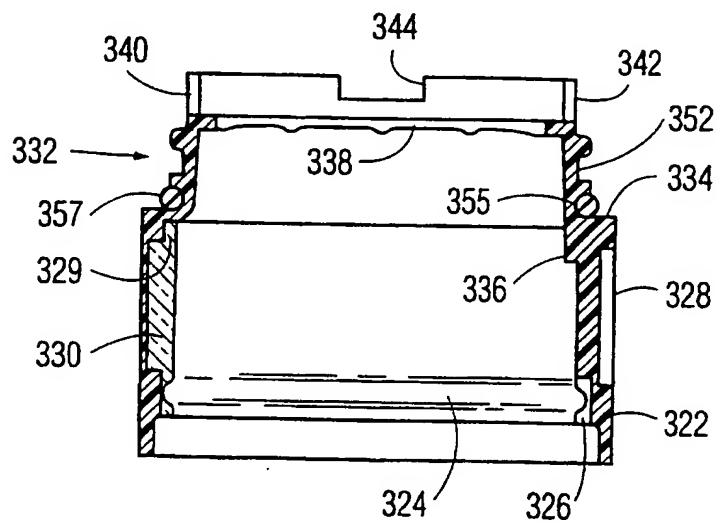


FIG. 44

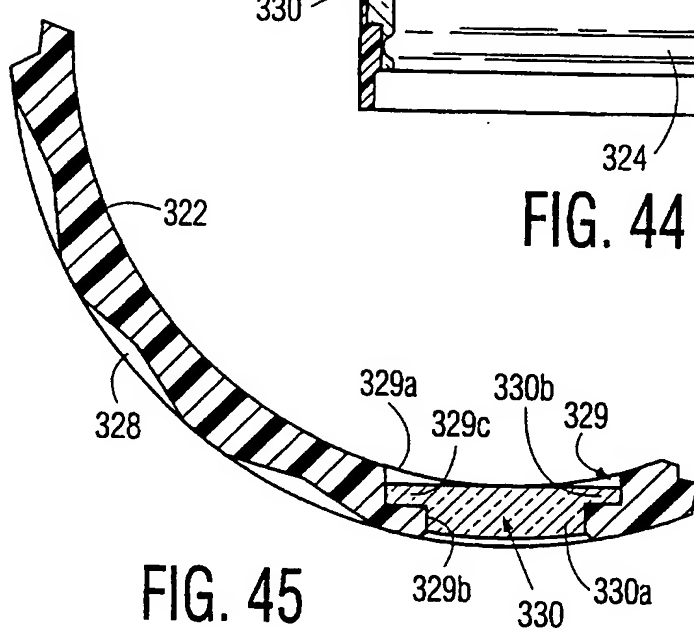


FIG. 45

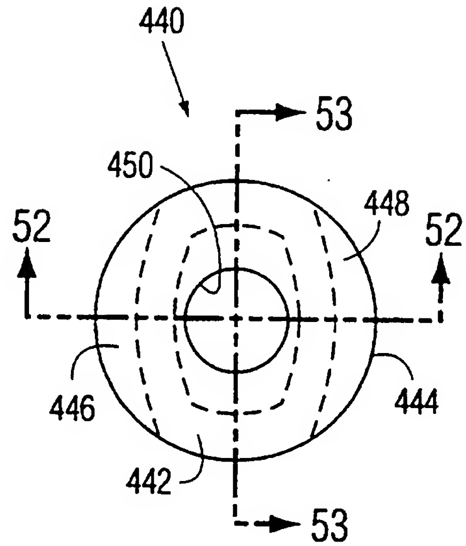


FIG. 51

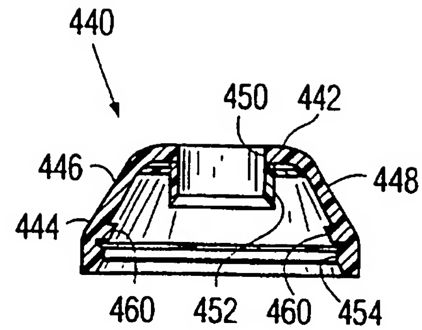


FIG. 52

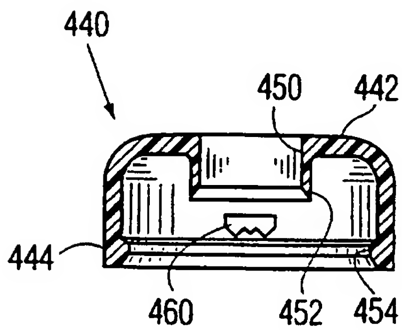


FIG. 53

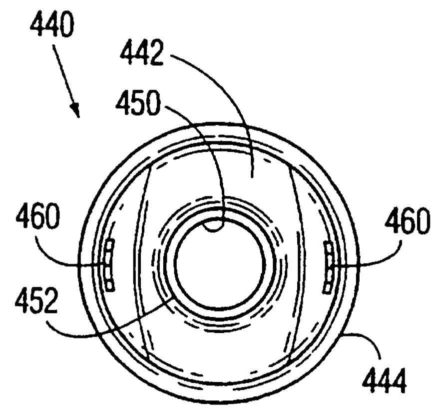


FIG. 54

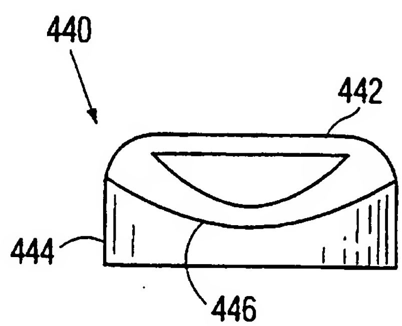


FIG. 55

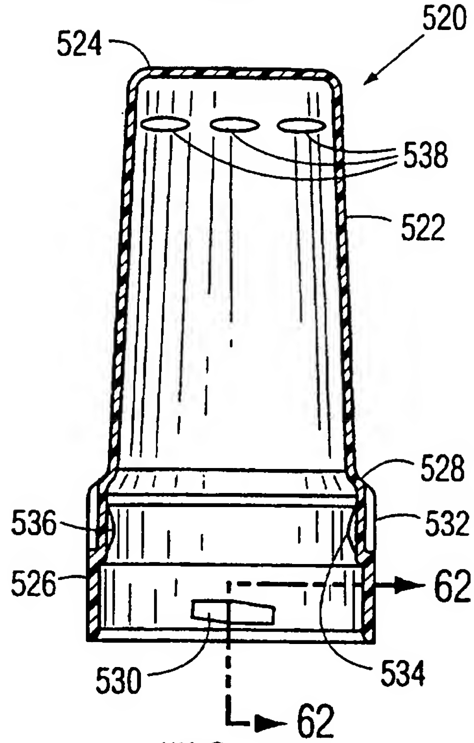

520
524
538
522
528
536
532
526
62
530
534
62

FIG. 59

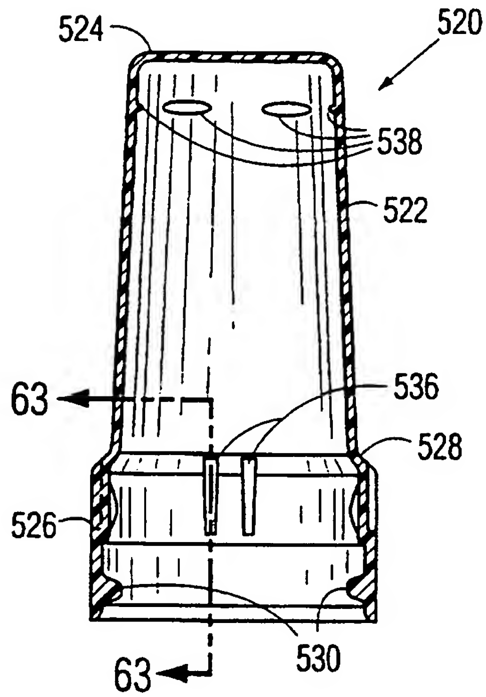

524
520
538
522
536
63
528
526
530
63

FIG. 60

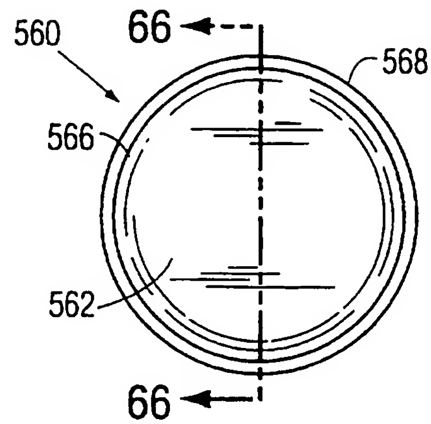


FIG. 64

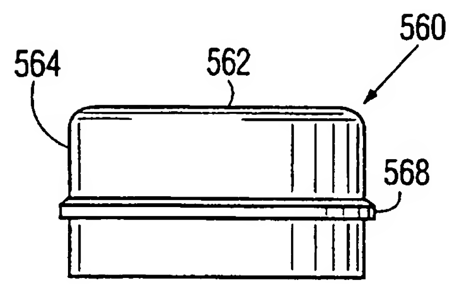


FIG. 65

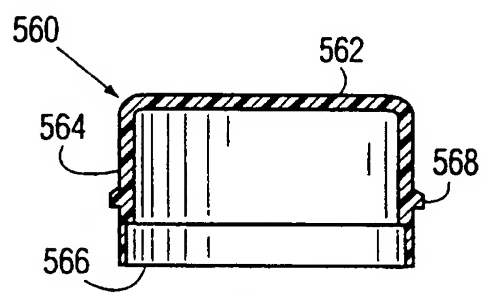


FIG. 66

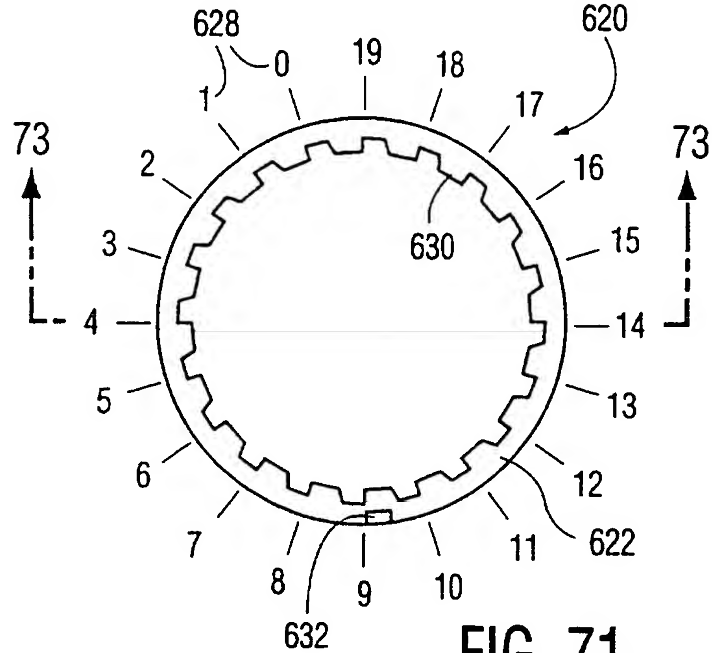


FIG. 71

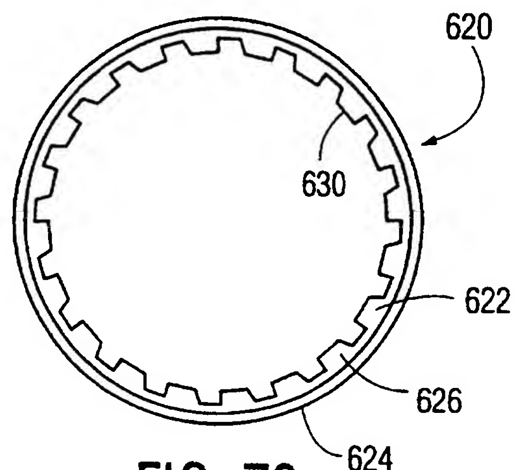


FIG. 72

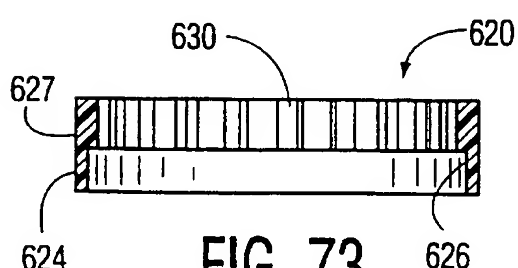


FIG. 73

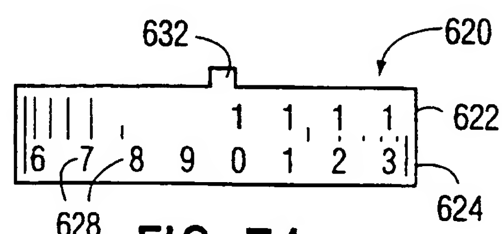


FIG. 74

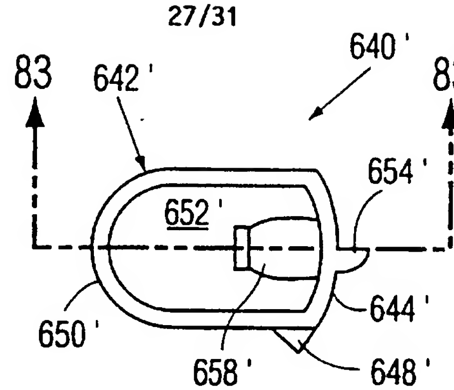


FIG. 80

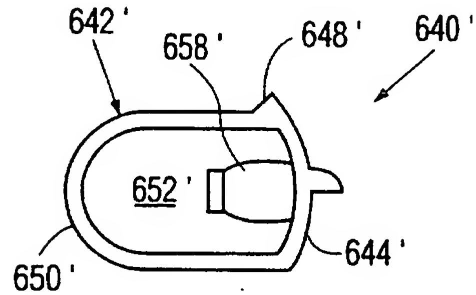


FIG. 81

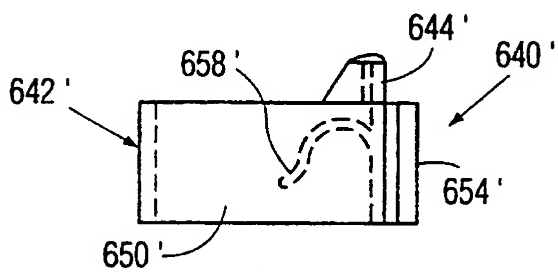


FIG. 82

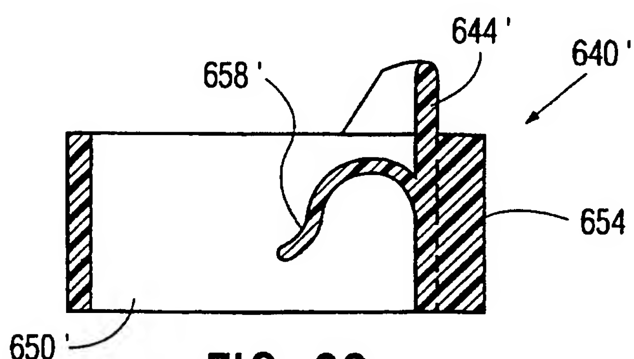


FIG. 83

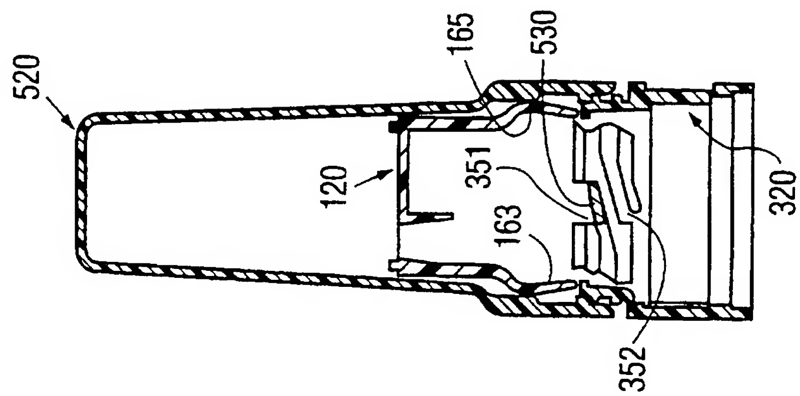


FIG. 89C

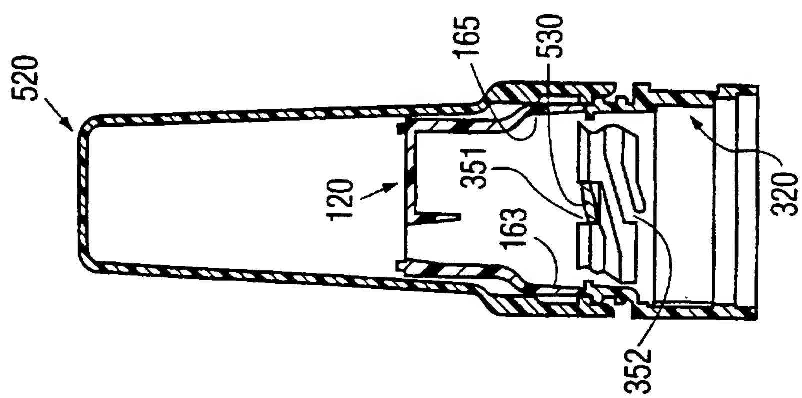


FIG. 89B

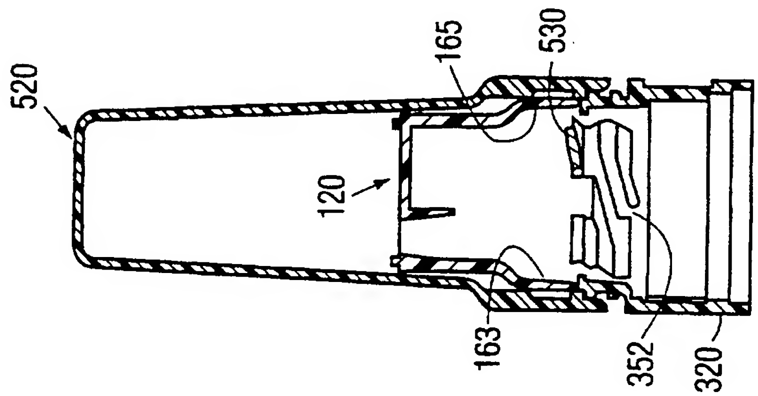


FIG. 89A

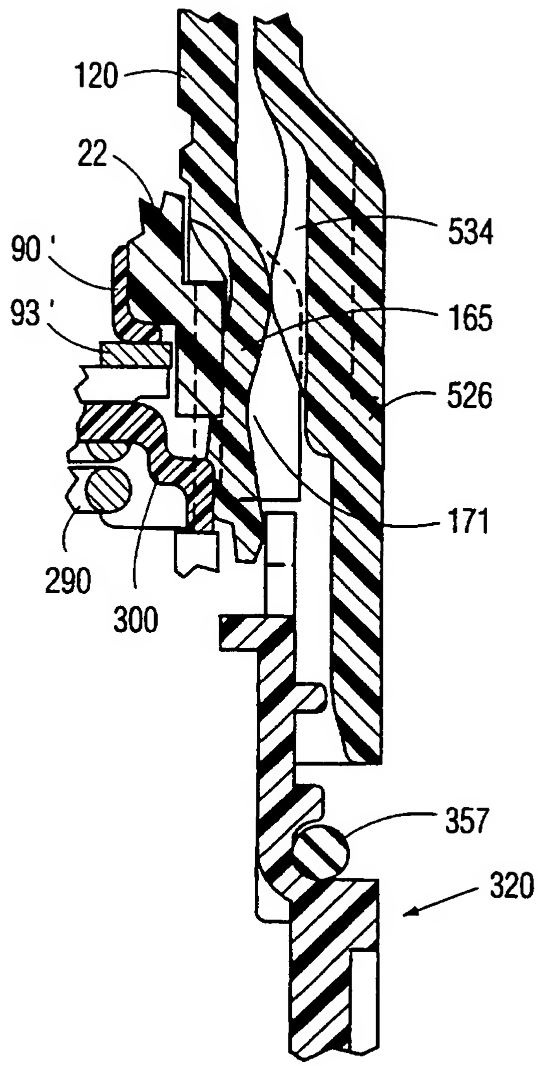


FIG. 90A

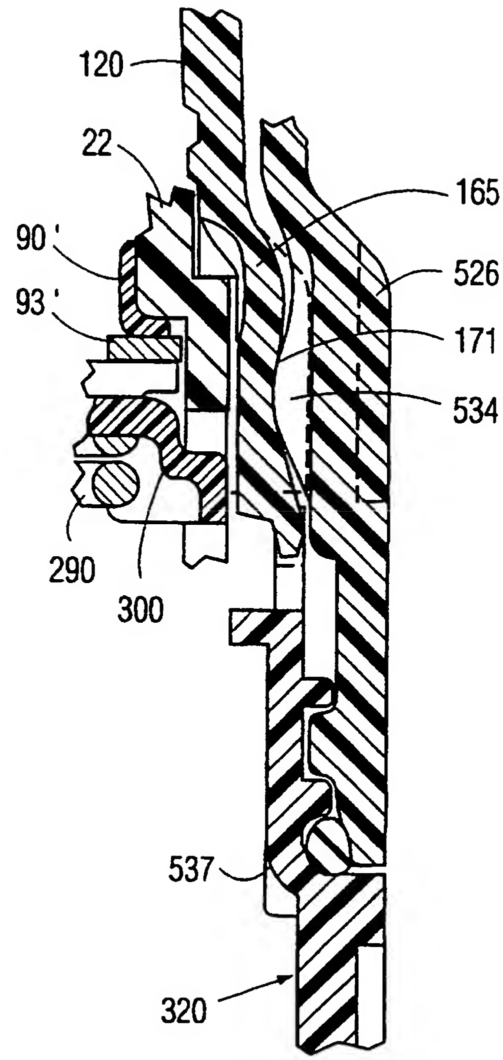


FIG. 90B